**Scott.A.Milkey**

**From:** Mark R Smith <dvg@[redacted]>
**Sent:** Friday, October 03, 2014 11:31 AM
**To:** Karns, Allison
**Subject:** Re: Introduction

The Da Vinci Group

Thinking For the 21st Century

*Washington Daily*

Perfect. 2pm EST. I'm at 202 [redacted] Thanks.

Regards,

Mark R. Smith

President

The Da Vinci Group

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Skype: [redacted]

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On Oct 3, 2014, at 11:22 AM, Karns, Allison <AKarns@gov.IN.gov> wrote:

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**From:** Mark R Smith [mailto:dvg@[redacted]]
**Sent:** Friday, October 03, 2014 10:32 AM
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**From:** Hill, John (DHS)
**Sent:** Thursday, October 02, 2014 4:12 PM
**To:** Karns, Allison
**Subject:** Re: Introduction

Okay.

From: Karns, Allison
Sent: Thursday, October 2, 2014 3:41 PM
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Subject: FW: Introduction

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**From:** Karns, Allison
**Sent:** Thursday, October 02, 2014 3:42 PM
**To:** Hill, John (DHS)
**Subject:** FW: Introduction
**Attachments:** AlcoholOutcomes,andPharmacotherapyPersistenceBaser_AJMC-2011.pdf.pdf; OutcomesofOpioid-DependenceTreatmentsBaser_AJMC-2011.pdf.pdf; PolicyDirectoryforCCCSubmission8-26-13.pdf; SAMHSA ADVISORY ON INTX 2012.pdf

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# Alcohol Dependence Treatments: Comprehensive Healthcare Costs, Utilization Outcomes, and Pharmacotherapy Persistence

Onur Baser, MS, PhD; Mady Chalk, PhD; Richard Rawson, PhD; and David R. Gastfriend, MD


## Abstract

**Objectives:** To determine the healthcare costs associated with treatment of alcohol dependence with medications versus no medication and across the 4 medications approved by the US Food and Drug Administration (FDA).

**Study Design:** Retrospective claims database analysis.

**Methods:** Eligible adults with alcohol dependence were identified from a large US health plan and the IMS PharMetrics Integrated Database. Data included all medical and pharmacy claims at all available healthcare sites. Propensity score–based matching and inverse probability weighting were applied to baseline demographic, clinical, and healthcare utilization variables for 20,752 patients, half of whom used an FDA-approved medication for alcohol dependence. A similar comparison was performed among 15,502 patients treated with an FDA-approved medication: oral acamprosate calcium (n = 8958), oral disulfiram (n = 3492), oral naltrexone (NTX) hydrochloride (n = 2391), or extended-release injectable naltrexone (XR-NTX; n = 661). Analyses calculated 6-month treatment persistence, utilization, and paid claims for: alcoholism medications, detoxification and rehabilitation, alcohol-related and nonrelated inpatient admissions, outpatient services, and total costs.

**Results:** Medication was associated with fewer admissions of all types. Despite higher costs for medications, total healthcare costs, including inpatient, outpatient, and pharmacy costs, were 30% lower for patients who received a medication for their alcohol dependence. XR-NTX was associated with greater refill persistence and fewer hospitalizations for any reason and lower hospital costs than any of the oral medications. Despite higher costs for XR-NTX itself, total healthcare costs were not significantly different from oral NTX or disulfiram, and were 34% lower than with acamprosate.

**Conclusion:** In this largest cost study to date of alcohol pharmacotherapy, patients who received medication had lower healthcare utilization and total costs than patients who did not. XR-NTX showed an advantage over oral medications in treatment persistence and healthcare utilization, at comparable or lower total cost.


*(Am J Manag Care. 2011;17:S222-S234)*

For author information and disclosures, see end of text.

Alcohol consumption is the third leading actual cause of death in the United States[1]; however, among the top 25 diseases, patients with alcohol-use disorders are least likely to receive care that is based upon evidence-based practice.[2] The overall cost to the United States for alcohol-related illness was estimated at $184 billion in 1998[3]; payers spend an estimated $9.7 billion annually on direct treatment of these disorders.[4] Historically, over 70% of these costs has been spent by public systems[4]; however, this proportion is expected to increasingly shift to the private pay sector in coming years as a result of federal parity and health care legislative reform. With a national prevalence of alcohol dependence of 3.8%, or 7.9 million adults,[5] these morbidity, mortality, and cost burdens are driving efforts to develop the most clinically effective and resource-efficient evidence-based treatments possible.



The dominant mode of treatment of alcohol dependence is psychosocial treatment or counseling, and several models have shown evidence for effectiveness.[6] Although 4 medications have been approved by the US Food and Drug Administration (FDA) for the treatment of alcohol dependence, there is little adoption of these agents.[7,8] Survey results published in 2007 reported that pharmacotherapies for substance-use disorders (SUDs) were offered in less than 25% of public and private specialty treatment programs[7] and a 2007 study reported that SUD medications comprised less than 1% of all SUD treatment costs.[8] Nevertheless, the National Institute on Alcohol Abuse and Alcoholism has issued recommendations stating that medications are "helpful to patients in reducing drinking, reducing relapse to heavy drinking, achieving and maintaining abstinence, or a combination of these effects" and clinicians should "consider adding medication whenever [they] are treating someone with active alcohol dependence."[6]

There are multiple reasons why medication-assisted treatment (MAT) for alcohol dependence is not widely used, including long-standing traditions rooted in the mutual help movement, but adoption of MAT is also predicated on concerns about poor patient adherence to medication, modest efficacy, and poor cost-effectiveness.[9-11] Retrospective insurance database studies of oral medications have reported that 50% of patients fail to obtain their first refill,[12,13] and refill rates are worse for alcoholism medications

than for statins and psychiatric medications.[14] Clinical trials have found that medication adherence is crucial to efficacy.[15]

Medication adherence in substance-dependence treatment has been a priority concern of the National Institutes of Health for over 3 decades.[16] In 2006, the FDA approved the first extended-release formulation for the treatment of alcohol dependence, extended-release naltrexone (XR-NTX), which was designed to address the challenge of adherence through a once-monthly injection.[17] Of the 4 agents FDA-approved for the treatment of alcohol dependence studied in a retrospective claims analysis of commercial insureds, XR-NTX was associated with reduced estimated charges and utilization of inpatient detoxification days and alcoholism-related inpatient days, compared with all 3 oral agents (ie, oral naltrexone, disulfiram, and acamprosate calcium).[18] Given the importance of alcohol dependence treatment for public health and healthcare cost containment, the present study was designed to extend current knowledge of real-world effectiveness with alcohol dependence treatments, including treatment with no medication, any approved medication, and among the approved medications, treatment with each specific agent. This study sought to examine a larger cohort of insured patients treated with XR-NTX than previously studied, and to determine a comprehensive range of healthcare utilization and actual expended healthcare costs for each treatment category.

## Methods

### *Data Sources and Study Population*

This was a retrospective database analysis conducted using commercial enrollees from a large US health plan affiliated with i3 Innovus and the PharMetrics Integrated Database from 2005 to 2009. These databases included medical and pharmacy claims from all available healthcare sites (inpatient, hospital outpatient, emergency department [ED], physician's office, and surgery center) for virtually all types of provided services, including specialty, preventive office-based treatments, and retail and mail order pharmacy claims.

For the comparison of the "no medication" group to the "any medication" group, patients were required have at least 1 claim for alcohol dependence (*Diagnostic and Statistical Manual of Mental Disorders, 4th Edition,* code 303.xx) during the pre- or post-index period, have an alcohol use disorder diagnosis pre-index, and have at least 6 months of continuous enrollment pre-index and 6 months post-index. The earliest pharmacy claim for alcohol medication was set as the index date for the any medication group. The index date was defined as the first medical claim for a nonpharmacologic treatment such as a detoxification facility claim, a substance abuse treatment facility claim, or a substance abuse counseling claim. Patients in the nonpharmacologic substance group had no prescription fills for alcoholism medication while patients in the any medication group had at least 1 fill for any of the 4 alcoholism medications. Patients with liver failure during the pre-index period were excluded. Furthermore, patients were excluded if they had claims for pharmacological treatment in the month prior to the index date (with the exception of the XR-NTX group, because this group was occasionally required to demonstrate prior oral medication failure). These inclusion/exclusion criteria led to a final sample of 20,670 patients in the no medication group and 15,502 patients in the any medication group. **Figure 1** presents the sample sizes after applying the inclusion/exclusion criteria.

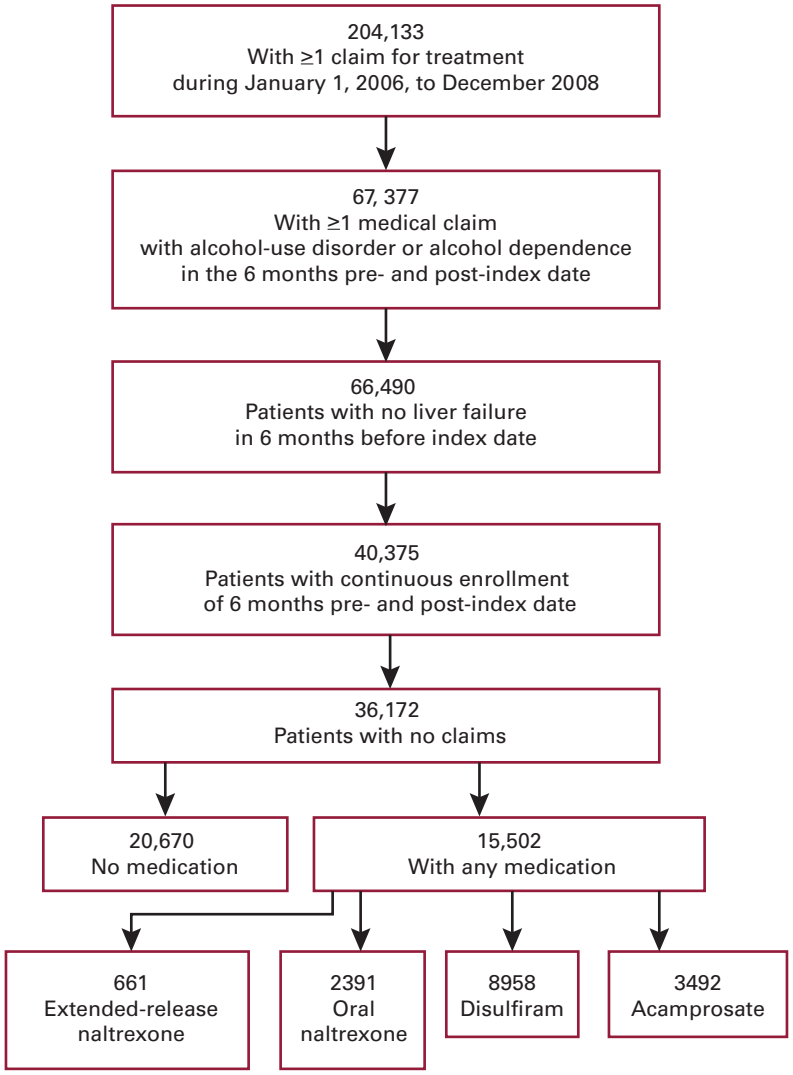
Similar criteria were required for patients in the comparison of the 4 alcoholism medications. Patients treated with XR-NTX were identified on the basis of an outpatient drug claim using the National Drug Code (NDC) or medical claims with the Healthcare Common Procedure Coding System code. The other medications, such as oral naltrexone, disulfiram, or acamprosate were identified using outpatient drug claims based on NDCs. The final sample of 661 patients in the XR-NTX group, 2391 patients in the oral NTX group, 8958 patients in the disulfiram group, and 3492 patients in the acamprosate group, was identified after applying the inclusion/exclusion criteria.

### *Statistical Analysis*

We derived demographic and clinical characteristics of the study populations at baseline. In particular, age, sex, and geographic location were measured at the index date. Deyo-Charlson comorbidity score,[19] Elixhauser score,[20] and the number of distinct psychiatric diagnoses and medications were calculated during the pre-index period. The Deyo-Charlson comorbidity score is an *International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM)* code adaption of the Charlson index, which assigns a range of weights, from 1 to 6 according to disease severity, for 19 conditions. The Elixhauser score is also a claims-based comorbidity index which sums a patient's comorbid conditions from among 30 *ICD-9-CM* comorbidity flags, differentiating secondary diagnoses from comorbidities by using diagnosis-related groups.

For socioeconomic status (SES), we constructed a summary measure for each US Zone Improvement Plan (ZIP) code using data on income, education, and occupation from the 2000 US Census and then linked this information to the patient's ZIP code of residence in the analytic files.[21] Factor analysis was used to identify 6 census variables that could be

**Figure 1.** Patient Selection Process




meaningfully combined into a summary socioeconomic status score. These variables included 3 measures of wealth/income (median household income, median value of housing units, and proportion of households with interest, dividend, or rental income), 2 measures of education (proportion of adult residents completing high school and college), and 1 measure of occupation/employment (proportion of employed residents with management, professional, and related occupations).[22]

Healthcare utilization and costs were calculated during both the pre-index and post-index periods. In terms of inpatient utilization, the number of detoxification facility days, and the number of detoxification and/or rehabilitation (admissions with an *ICD-9-CM* procedure for detoxification or rehabilitation), alcohol (admission with a principal diagnosis), and nonrelated inpatient admissions were measured. ED visits, alcohol-related physician visits, alcohol and substance abuse psychosocial provider visits, and non–alcohol-related outpatient visits were calculated. Utilization measures were presented per 1000 patients. Associated costs related to these measures and total costs were also calculated.

In addition to healthcare utilization and costs, we evaluated adherence by analyzing medication possession ratio and days of persistence with index medication refills post-index date.

Baseline characteristics were compared between the patient cohorts, and descriptive statistics were calculated as percentages and standard deviations. Differences between the cohorts were analyzed using the *t*-test, Mann-Whitney U test, and $\chi^2$ test, and standardized differences were calculated. It has been demonstrated that standardized differences 10% and higher between the baseline variables are significant, and need to be adjusted to compare the outcome measures among the groups.[23,24]

Propensity-score matching was applied to compare the risk-adjusted outcomes between the no medication group and the any medication group. Propensity-score matching is a technique that aims at adjusting for selection bias in nonexperimental, nonrandomized, and retrospective studies like the present one.[25] By using propensity-score matching, each patient in the any medication group was "mirrored" by a patient with similar predefined characteristics in the no medication group. The following characteristics were used to match: age, sex, region, comorbid scores, SES, baseline healthcare utilization, and costs. Logistic regression was used to estimate propensity scores. Several interaction variables were constructed, but they were not determined to be significant. Estimation power of the logistic regression was determined by C statistics. Following the guidelines set forth by Baser, it was determined that one-to-one matching created the best balance among the groups.[26]

Following Imbens and Lechner, we applied propensity-score matching that accounts for multilevel treatments when comparing the 4 alcoholism medication groups.[27,28] Several applications of this method are presented in the medical literature.[29-31] The first step uses multinomial logistic regression

**Table 1.** Risk-Adjusted Baseline Characteristics of Alcohol-Dependent Patients With Any Versus No Medication

| Pre-Index Period (6-month period before index date) | Alcohol-Dependent Patients (each group has N = 10,376) Any medication | No medication | |
|---|---|---|---|
| **Continuous variables** | **Mean (SD)** | **Mean (SD)** | ***P*** |
| **Healthcare utilization** | | | |
| **Pre-index number of detox facility days (number of days/1000 patients)** | 79 (938) | 65 (779) | .2366 |
| **Pre-index inpatient (number of admissions/1000 patients)** | | | |
| Detoxification and/or rehabilitation | 15 (147) | 14 (135) | .5553 |
| Alcohol-related inpatient admission | 139 (436) | 125 (427) | **.0244** |
| Non–alcohol-related inpatient admission | 264 (607) | 273 (632) | .2625 |
| **Pre-index outpatient (number of visits/1000 patients)** | | | |
| Emergency department visit | 734 (1968) | 778 (2149) | .1236 |
| Alcohol-related and physician provider | 774 (3835) | 487 (3110) | **<.0001** |
| Alcohol-related and substance abuse psychosocial provider | 521 (3797) | 374 (2585) | **.0011** |
| Non–alcohol-related outpatient admission | 10,602 (11,063) | 9846 (11,035) | **<.0001** |
| **Costs (per patient)** | | | |
| **Pre-index inpatient** | | | |
| Cost of detoxification and/or rehabilitation | $30 ($493) | $0 ($0) | **<.0001** |
| Cost of alcohol-related inpatient admission | $720 ($4315) | $650 ($3909) | .2224 |
| Cost of non–alcohol-related inpatient admission | $2059 ($8297) | $2545 ($10,659) | **.0002** |
| **Pre-index outpatient** | | | |
| Cost of emergency department visit | $207 ($693) | $244 ($850) | **.0006** |
| Cost of alcohol-related and physician provider | $94 ($731) | $72 ($817) | **.0403** |
| Cost of alcohol-related and substance abuse | $50 ($355) | $25 ($259) | **<.0001** |
| Cost of non–alcohol-related outpatient admission | $21 ($25) | $20 ($27) | **.0107** |
| **Pre-index pharmacy** | | | |
| Cost of FDA-approved alcohol dependence medications | $5 ($45) | $0 ($0) | **<.0001** |
| Cost of other psychiatric medications | $122 ($427) | $62 ($307) | **<.0001** |
| Cost of nonpsychiatric medications | $361 ($899) | $247 ($806) | **<.0001** |
| **Total cost (per patient = inpatient + outpatient + pharmacy)** | $5922 ($11,439) | $6174 ($13,726) | .1519 |

FDA indicates US Food and Drug Administration.

to estimate conditional probabilities of being in the particular treatment group. The second and final step estimates conditional expectation of outcome given the treatment level. Adjusted Wald tests were performed to test for the difference in weighted characteristics across the treatment cohorts.

Statistical analyses were performed using SAS v9.2 (SAS Institute, Cary, North Carolina) and STATA v10 (Stata Corp, College Station, Texas).

## Results

The risk-adjusted pre-index characteristics of 10,376 patients matched between each of the 2 groups (any medication and no medication, respectively) showed the following similarities: age, (44.4 vs 44.5 years; *P* = not significant [NS]); sex (male, 61.8% vs 61.9%; *P* = NS); geographic region (Eastern, 18.4% vs 18.0%; *P* = NS); SES score (high SES, 29.2% vs 29.2%; *P* = NS); and pre-index severity (proxied by having a ≥3 Elixhauser Index score, 25.2% vs 25.1%; *P* = .06). Differences in the Deyo-Charlson comorbidity score (0.34 vs 0.38; *P* =.0002) and Elixhauser Comorbid conditions (1.63 vs 1.57; *P* = .0034) were significant, but in opposite directions. During the pre-index period, the number of distinct psychiatric diagnoses and medications were higher in patients in the any medication group compared with the no

medication group (2.71 vs 2.32 and 1.68 vs 1.29, respectively; both $P$ <.0001).

Table 1 shows that, on average, detoxification admissions per 1000 patients in the any medication and no medication groups were similar (15 vs 14, respectively). Outpatient visits were significantly higher for patients in the any medication group. In particular, per 1000 patients, alcohol-related physician provider visits (774 vs 487) and non–alcohol-related outpatient visits (10,602 vs 9846) were significantly higher for the any medication group than the no medication group. The largest driver of pre-index treatment costs, however, was the cost of non–alcohol-related inpatient admission ($2059 vs $2545 per patient). After risk adjustment, the baseline costs in the any medication group were $5922 per patient versus $6174 per patient in the no medication group.

Table 2 presents the risk-adjusted outcome results. Patients in the no medication group stayed more days in detoxification facilities post-index relative to patients in the any medication group (3497 vs 483 days per 1000 patients). They had significantly more psychiatric diagnoses during the post-index period (3.19 vs 3.07). Post-index detoxification and/or rehabilitation admissions (563 vs 85), alcohol (660 vs 202), and nonalcohol (407 vs 257) admissions were significantly higher per 1000 patients in the no medication group. Higher admission days for the no medication group in detoxification and/or rehabilitation translated to a cost burden of $1350 versus $209 per patient in the any medication group. Costs for alcohol-related admissions were $2464 versus $801, and $2751 versus $2336 for non–alcohol-related inpatient admissions, respectively.

The pattern of greater utilization and costs also existed among patients in the no medication group for outpatient visits. This group was more likely to have physician provider visits (1970 vs 1454), psychosocial provider visits (1740 vs 991), and non–alcohol-related outpatient visits (14,101 vs 13,349) per 1000 patients. This translated into a greater cost burden of $106 per patient due to more physician provider visits and $61 due to more psychosocial provider visits. The 6-month total healthcare cost for a patient in the no medication group was $11,677 versus $8134 in the any medication group.

Among 15,502 patients who used any pharmacologic drug, 661 patients were treated with XR-NTX, 2391 with oral NTX, 3492 with disulfiram, and 8958 with acamprosate. Patients in the XR-NTX group were slightly older (45.91 years vs 44.24, $P$ <.001; 43.53, $P$ <.0001; 45.63, $P$ = NS, respectively). There were no differences in the percentages of males in the groups (60% vs 58%, 62%, 59%; all $P$ = NS). However, patients given XR-NTX resided more commonly in the East (34.0% vs 26%, 16%, 18%; all $P$ <.0001) and South (31% vs 19%, 16%, 26%; all $P$ <.01) compared with the Midwest and West. There was no clear pattern of SES differences among the 4 groups.

Table 3 presents the pre-index clinical, utilization, and cost characteristics of the 4 alcohol medication groups. In terms of severity (proxied by percentage with a ≥3 Elixhauser score) the XR-NTX group (31.0%) did not differ in high comorbidity rates relative to oral NTX (34.5%) or disulfiram (28.4%), but it was significantly lower compared with those given acamprosate (37.9%, $P$ = .0004). However, patients in the XR-NTX group had a higher use of distinct psychiatric medication relative to the other groups. Compared with patients in the XR-NTX cohort, during the pre-index period, those receiving acamprosate had significantly more detoxification facility days, and those given disulfiram had significantly fewer. Also, the acamprosate group had more detoxification and/or rehabilitation admissions and alcohol- and non–alcohol-related admissions compared with those in the XR-NTX group. During the pre-index period, the number of non–alcohol-related outpatient visits was significantly higher in the XR-NTX group relative to others.

The total healthcare costs were significantly higher for patients in the XR-NTX group compared with those in the oral NTX and the disulfiram groups, but there were no differences in pretreatment costs between XR-NTX and acamprosate.

After adjusting for these baseline differences, the risk-adjusted outcome results for the 4 groups are presented in Table 4. Patients receiving XR-NTX had significantly higher refill adherence rates than patients in the other groups (21% vs 11% for oral NTX, 9% for disulfiram, and 6% for acamprosate). The number of persistence days was also significantly higher (61.6 days vs 49.8 days with oral naltrexone, 45.8 days with disulfiram, and 42.6 days with acamprosate) (Figure 2A). Patients receiving XR-NTX had a significantly lower number of distinct diagnoses relative to those given acamprosate (3.05 vs 3.30), and a lower number of psychiatric medications relative to those given disulfiram (1.96 vs 2.80).

Inpatient healthcare utilization in the XR-NTX group was significantly lower than that in the other groups. Patients given XR-NTX spent significantly fewer days in a detoxification facility relative to those given disulfiram or acamprosate (227 days vs 429 days vs 741 days per 1000 patients, respectively). Detoxification and/or rehabilitation admission and alcohol- and non–alcohol-related admission were significantly lower in the XR-NTX group relative to the other groups ($P$ <.01) (Figure 2B). This translated

**Table 2.** Risk-Adjusted Outcomes in Alcohol-Dependent Patients With Any Versus No Medication

| Post-Index Period (6 months after index date) | Alcohol-Dependent Patients (each group has N = 10,376) | | |
|---|---|---|---|
| | Any medication | No medication | |
| **Outcome** | **Mean (SD)** | **Mean (SD)** | ***P*** |
| **Post-index number of distinct psychiatric diagnoses** | 3.07 (1.78) | 3.19 (1.71) | **<.0001** |
| **Post-index number of distinct psychiatric medication** | 2.25 (1.83) | 1.39 (1.56) | **<.0001** |
| **Healthcare utilization** | | | |
| **Post-index number of detoxification facility days (number of days/1000 patients)** | 483 (2489) | 3497 (7293) | **<.0001** |
| **Post-index inpatient (number of admissions/1000 patients)** | | | |
| Detoxification and/or rehabilitation | 85 (336) | 563 (641) | **<.0001** |
| Alcohol-related inpatient admission | 202 (562) | 660 (863) | **<.0001** |
| Non–alcohol-related inpatient admission | 257 (650) | 407 (757) | **<.0001** |
| **Post-index outpatient (number of visits/1000 patients)** | | | |
| Emergency department visit | 787 (2352) | 648 (2169) | **<.0001** |
| Alcohol-related and physician provider | 1454 (5266) | 1970 (6064) | **<.0001** |
| Alcohol-related and substance abuse psychosocial provider | 991 (4425) | 1740 (5781) | **<.0001** |
| Non–alcohol-related outpatient | 13,349 (12,919) | 14,101 (14,126) | **.0007** |
| **Costs (per patient)** | | | |
| **Post-index inpatient** | | | |
| Cost of detoxification and/or rehabilitation | $209 ($1140) | $1350 ($2863) | **<.0001** |
| Cost of alcohol-related inpatient admission | $801 ($3749) | $2464 ($7025) | **<.0001** |
| Cost of non–alcohol-related inpatient admission | $2336 ($12,492) | $2751 ($13,815) | **<.0001** |
| **Post-index outpatient** | | | |
| Cost of emergency department visit | $207 ($744) | $173 ($695) | **<.0001** |
| Cost of alcohol-related physician provider | $199 ($988) | $305 ($1204) | **<.0001** |
| Cost of alcohol-related substance abuse psychosocial provider | $87 ($440) | $148 ($605) | **<.0001** |
| Cost of non–alcohol-related | $25 ($29) | $27 ($32) | .0592 |
| **Post-index pharmacy** | | | |
| Cost of FDA-approved alcohol dependence medications | $350 ($637) | $1 ($17) | **<.0001** |
| Cost of other psychiatric medications | $228 ($677) | $95 ($427) | **<.0001** |
| Cost of nonpsychiatric medications | $523 ($1153) | $291 ($967) | **<.0001** |
| **Total cost (per patient = inpatient + outpatient + pharmacy)** | $8134 ($15,887) | $11,677 ($19,889) | **<.0001** |

FDA indicates US Food and Drug Administration.

to lower inpatient costs per patient for detoxification and rehabilitation (XR-NTX: $105 vs $192 with oral NTX, $203 with disulfiram, and $288 with acamprosate), alcohol-related inpatient admission (XR-NTX: $474 vs $618 with oral NTX, $874 with disulfiram, and $1166 with acamprosate), and non–alcohol-related admission (XR-NTX: $730 vs $1091 with oral naltrexone, $1498 with disulfiram, and $3885 with acamprosate).

Although outpatient healthcare utilization was similar across the groups, the average patient receiving XR-NTX had higher 6-month costs for ED visits ($272) vs oral agents ($227 with oral naltrexone, $227 with disulfiram, and $209 with acamprosate), and lower costs for alcohol-related physician provider visits (XR-NTX: $67 vs $107 oral NTX, $118 with disulfiram, and $291 with acamprosate) and alcohol and substance abuse outpatient visits (XR-NTX: $46 vs $76 with oral NTX, $114 with disulfiram, and $82 with acamprosate). XR-NTX was associated with higher costs for non–alcohol-related outpatient visits (NXT-XR: $4510 vs $3444 with oral NTX, $3194 with disulfiram, and $3589 with acamprosate).

**Table 3.** Baseline Characteristics of Alcohol-Dependent Patients by Pharmacotherapy

| Pre-Index Period (6-month period before index date) | XR-NTX (n = 661) |
|---|---|
| **Continuous variables** | **Mean (SD)** |
| **Clinical characteristics** | |
| Pre-index Deyo-Charlson comorbidity score | 0.41 (0.91) |
| Pre-index Elixhauser comorbid conditions | 1.91 (1.71) |
| Pre-index number of distinct psychiatric diagnoses | 3.20 (1.89) |
| Pre-index number of distinct psychiatric medication | 2.00 (1.79) |
| **Healthcare utilization** | |
| Pre-index number of detoxification facility days number of days/1000 patients) | 1212 (3802) |
| **Pre-index inpatient (number of admissions/1000 patients)** | |
| Detoxification and/or rehabilitation | 215 (536) |
| Alcohol-related inpatient admission | 380 (840) |
| Non–alcohol-related inpatient admission | 333 (766) |
| **Pre-index outpatient (number of visits/1000 patients)** | |
| Emergency department visits | 911 (2234) |
| Alcohol-related and physician provider | 773 (3785) |
| Alcohol-related and substance abuse psychosocial provider | 490 (2465) |
| Non–alcohol-related outpatient | 12,470 (12,239) |
| **Costs (per patient)** | |
| **Pre-index inpatient** | |
| Cost of detoxification and/or rehabilitation | $688 ($2344) |
| Cost of alcohol-related inpatient admission | $1638 ($6032) |
| Cost of non–alcohol-related inpatient admission | $2504 ($8362) |
| **Pre-index outpatient** | |
| Cost of emergency department visits | $244 ($700) |
| Cost of alcohol-related and physician provider | $82 ($468) |
| Cost of alcohol-related and substance abuse psychosocial provider | $53 ($329) |
| Cost of non–alcohol-related | $25 ($27) |
| **Pre-index pharmacy** | |
| Cost of FDA-approved alcohol dependence medications | $100 ($174) |
| Cost of other psychiatric medications | $163 ($486) |
| Cost of nonpsychiatric medications | $553 ($1436) |
| **Total cost (per patient = inpatient + outpatient + pharmacy)** | $9467 ($13,988) |

FDA indicates US Food and Drug Administration; NTX, naltrexone; XR-NTX, extended-release injectable naltrexone.

Post-index pharmacy costs were higher for the XR-NTX group; cost savings from inpatient and outpatient admissions, however, resulted in total costs that were significantly lower in patients given XR-NTX compared with those given acamprosate ($6757 vs $10,345 per patient). Significant differences in overall costs were not observed among the NXT-XR group and other groups.

## Discussion

Access to the combined data from these 2 large insurance data sets allowed for the examination of clinical outcomes and costs/benefits associated with available types of alcoholism treatments (as employed in the US healthcare system), resulting in the largest health economic evaluation of alcoholism treatments reported to date in the literature.

| Alcohol-Dependence Pharmacotherapy | | | | | |
|---|---|---|---|---|---|
| Oral NTX (n = 2391) | | Disulfiram (n = 3492) | | Acamprosate (n = 8958) | |
| Mean (SD) | *P* | Mean (SD) | *P* | Mean (SD) | *P* |
| 0.33 (0.82) | **.0280** | 0.33 (0.92) | **.0233** | 0.40 (0.97) | .7860 |
| 2.04 (1.73) | .0850 | 1.74 (1.71) | **.0262** | 2.17 (1.75) | **.0001** |
| 3.14 (1.92) | .4632 | 2.91 (1.96) | **.0004** | 3.08 (1.84) | .1228 |
| 1.78 (1.68) | **.0055** | 1.73 (1.67) | **.0003** | 1.70 (1.64) | **<.0001** |
| 1376 (4169) | .3375 | 803 (2805) | **.0086** | 1644 (3956) | **.0051** |
| 226 (525) | .6384 | 165 (463) | **.0253** | 294 (529) | **.0003** |
| 350 (642) | .3997 | 313 (704) | .0553 | 469 (685) | **.0078** |
| 377 (686) | .1775 | 297 (653) | .2553 | 412 (735) | **.0107** |
| 810 (2055) | .2954 | 840 (2209) | .4560 | 772 (1993) | .1207 |
| 622 (3155) | .3486 | 1009 (4657) | .1582 | 657 (3346) | .4420 |
| 410 (5661) | .5933 | 782 (3643) | **.0107** | 347 (2187) | .1468 |
| 11,359 (11,964) | **.0381** | 10,877 (11,930) | **.0021** | 10,757 (10,804) | **.0005** |
| $571 ($2000) | .2407 | $313 ($1275) | **.0001** | $708 ($1890) | .8334 |
| $1360 ($4333) | .2669 | $1056 ($4452) | **.0183** | $1660 ($5759) | .9304 |
| $2476 ($7975) | .9396 | $2420 ($19,299) | .8555 | $2619 ($9331) | .7336 |
| $252 ($789) | .8013 | $266 ($990) | .5018 | $225 ($740) | .5050 |
| $86 ($602) | .8563 | $122 ($743) | .0740 | $91 ($773) | .6581 |
| $38 ($312) | .2870 | $89 ($506) | **.0203** | $35 ($312) | .1620 |
| $23 ($25) | **.0273** | $22 ($29) | **.0040** | $22 ($25) | **.0017** |
| $0 ($0) | **<.0001** | $0 ($0) | **<.0001** | $0 ($0) | **<.0001** |
| $145 ($525) | .4096 | $109 ($394) | **.0069** | $114 ($398) | **.0118** |
| $373 ($854) | **.0021** | $308 ($838) | **<.0001** | $360 ($858) | **.0007** |
| $8031 ($12,113) | **.0165** | $6904 ($21,495) | **.0001** | $9543 ($118,914) | .9556 |

This risk-adjusted analysis compared 20,752 patients who received any versus no medication, and 15,502 patients who received 1 of the 4 FDA-approved medications. A total of 661 patients received treatment with XR-NTX, making this the largest sample studied to date with this particular treatment. In addition, the study involved a comprehensive analysis of actual total healthcare costs paid and healthcare service utilization. Results showed that, compared with alcohol dependence treatment that did not include medication, medication-assisted treatment was associated with significantly fewer admissions for detoxification and/or rehabilitation, alcohol-related inpatient medical care, and non–alcohol-related inpatient medical care. Costs for services in all of these inpatient categories were significantly lower in

**Table 4.** Risk-Adjusted Outcome Measures in Alcohol-Dependent Patients by Pharmacotherapy

| | Alcohol-Dependence Pharmacotherapy | | | | | | |
|---|---|---|---|---|---|---|---|
| **Post-Index Period (6 months after index date)** | **XR-NTX (n = 661)** | **Oral NTX (n = 2391)** | | **Disulfiram (n = 3492)** | | **Acamprosate (n = 8958)** | |
| **Compliance and persistence with therapy** | **%** | **%** | ***P*** | **%** | ***P*** | **%** | ***P*** |
| Continuous MPR ≥0.8 | 21 | 11 | **<.0001** | 9 | **<.0001** | 6 | **<.0001** |
| **Outcome** | **Mean** | **Mean** | ***P*** | **Mean** | ***P*** | **Mean** | ***P*** |
| Persistence days with index medication | 61.65 | 49.75 | **.00** | 45.81 | **.00** | 42.56 | **.00** |
| Post-index number of distinct psychiatric diagnoses | 3.05 | 2.94 | .20 | 3.04 | .89 | 3.30 | **.04** |
| Post-index number of distinct psychiatric medications | 1.96 | 1.98 | .78 | 2.80 | **.00** | 2.10 | .20 |
| **Healthcare utilization** | | | | | | | |
| Post-index number of detoxification facility days (number of days/1000 patients) | 227 | 361 | .1442 | 429 | **.0472** | 741 | **.0039** |
| **Post-index inpatient (number of admissions/1000 patients)** | | | | | | | |
| Detoxification and/or rehabilitation | 43 | 76 | **.0039** | 98 | **.0001** | 120 | **.0001** |
| Alcohol-related inpatient admission | 82 | 184 | **<.0001** | 268 | **<.0001** | 317 | **<.0001** |
| Non–alcohol-related inpatient admission | 109 | 205 | **<.0001** | 250 | **<.0001** | 343 | **<.0001** |
| **Post-index outpatient (number of visits/1000 patients)** | | | | | | | |
| Emergency department visits | 903 | 817 | .5017 | 823 | .5604 | 809 | .5742 |
| Alcohol-related and physician provider | 1053 | 1154 | .7007 | 1140 | .7543 | 1678 | .1733 |
| Alcohol-related and substance abuse psychosocial provider | 705 | 999 | .1940 | 1171 | .0825 | 805 | .6922 |
| Non–alcohol-related outpatient | 14,414 | 12,726 | **.0086** | 13,159 | .0696 | 14,429 | .9868 |
| **Cost (per patient)** | | | | | | | |
| **Post-index inpatient** | | | | | | | |
| Cost of detoxification and/or rehabilitation | $105 | $192 | **<.0001** | $203 | **<.0001** | $288 | **<.0001** |
| Cost of alcohol-related inpatient admission | $474 | $618 | **<.0001** | $874 | **<.0001** | $1166 | **<.0001** |
| Cost of non–alcohol-related inpatient admission | $730 | $1091 | **<.0001** | $1498 | **<.0001** | $3885 | **<.0001** |
| **Post-index outpatient** | | | | | | | |
| Cost of emergency department visits | $272 | $227 | **.0007** | $227 | **.0011** | $209 | **.0001** |
| Cost of alcohol-related and physician provider | $67 | $107 | **<.0001** | $118 | **<.0001** | $291 | **<.0001** |
| Cost of alcohol-related and substance abuse psychosocial provider | $46 | $76 | **<.0001** | $114 | **<.0001** | $82 | **<.0001** |
| Cost of non–alcohol-related | $4510 | $3444 | **<.0001** | $3194 | **<.0001** | $3589 | **.0008** |
| **Post-index pharmacy** | | | | | | | |
| Cost of FDA-approved alcohol dependence medications | $2230 | $200 | **<.0001** | $209 | **<.0001** | $292 | **<.0001** |
| Cost of other psychiatric medications | $326 | $232 | **<.0001** | $168 | **<.0001** | $229 | **<.0001** |
| Cost of nonpsychiatric medications | $600 | $477 | **<.0001** | $417 | **<.0001** | $537 | .1160 |
| **Total cost (per patient = inpatient + outpatient + pharmacy)** | $6757 | $6595 | .6431 | $7107 | .3601 | $10,345 | **<.0001** |

FDA indicates US Food and Drug Administration; MPR, medication possession ratio; NTX, naltrexone; XR-NTX, extended-release injectable naltrexone.

patients who received a medication, and (despite significantly higher costs for medications) total healthcare costs, including inpatient, outpatient, and pharmacy costs, were 30% lower for patients who received a medication for their alcohol dependence. With XR-NTX, cost data associated with hospital admissions and stays reflected a similar picture. Hospital costs for patients receiving XR-NTX were significantly and substantially lower than those for patients receiving 1 of the 3 oral medications. Patients given XR-NTX used fewer days in detoxification and had fewer admissions to the hospital for any reason than patients given 1 of the 3 oral medications.

Costs for services in all of these inpatient categories were significantly lower for patients who received XR-NTX, and despite significantly higher costs for XR-NTX, total healthcare costs, including inpatient, outpatient, and pharmacy costs, were not significantly different from total costs with oral NTX or disulfiram, and were 34% lower than with acamprosate.

The frequency of hospital admission is an intensive utilization and cost-related variable and may also represent a proxy for morbidity, in the absence of direct clinical data (which is lacking with retrospective claims data such as these). As such, reduced hospitalization, which is obviously important in cost reduction, is also an important objective in its own right. For example, medication was associated with 30% lower costs than no medication treatment; compared with no medication treatment, the relative risk reduction associated with medication was 85% for admission to detoxification or rehabilitation, and 69% for alcohol-related admission. Among the 4 medications, total costs with XR-NTX were not significantly different from oral NTX and disulfiram, and they were 34% lower than those with acamprosate. XR-NTX was associated with relative risk reductions for admission to detoxification/rehabilitation of 43% versus oral NTX, 56% versus disulfiram, and 64% versus acamprosate, and reductions for admission to alcohol-related hospitalization of 55% versus oral NTX, 69% versus disulfiram, and 74% versus acamprosate.

These reductions showed an inverse association with refill persistence (Figure 2A). One of the most important challenges in the use of alcohol pharmacotherapies is retaining patients in treatment (on medication) for clinically adequate durations. In the 2 measures of treatment duration, participants receiving XR-NTX were retained significantly longer and more continuously on medication than participants receiving oral medications. Of the 4 agents, the 2 compliance parameters, persistence (days with index medication) and continuous mean possession ratio greater than 80% of days, both showed a similar pattern (in increasing order of persistence): acamprosate, disulfiram, oral NTX, and XR-NTX. This pattern closely follows the burden of medication administration: acamprosate, 2 tablets 3 times daily; disulfiram and oral NTX, 1 tablet once daily (oral NTX is sometimes given in higher doses every other day); and XR-NTX, 1 injection per month. Also, the pattern of persistence is opposite the rate of admissions with the 4 medications (Figure 2B).

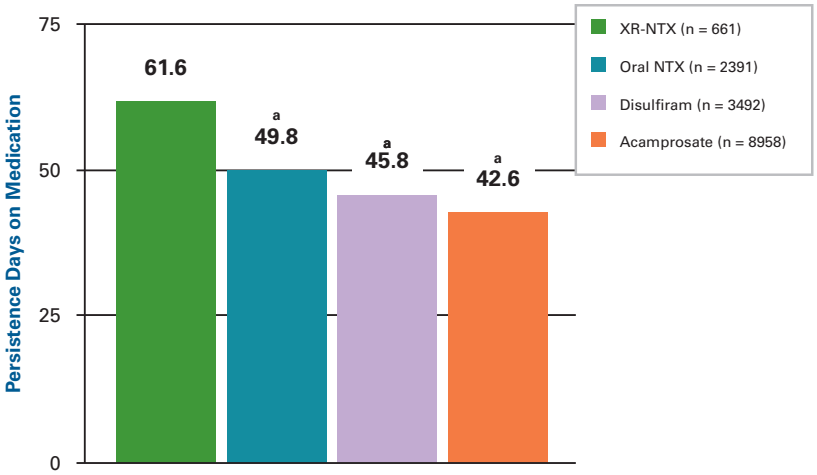
The cost differences found in these comparisons are revealing, because the group treated with any medication had overall medication costs that were more than double the medication costs (ie, nonalcoholism medications) of those with no alcoholism medications. Yet, their total healthcare costs were less. Similarly, the cost of XR-NTX alone was up to 10-fold higher than that for the oral alcohol dependence agents (some of which are available as generic products). Total healthcare costs, however, were either associated with no difference or lower expense. This finding suggests that the cost of a particular treatment should not be confused with the overall cost of care and that the overall objective of quality and efficient healthcare needs to transcend the compartmentalization of costs within pharmacy benefit management versus overall healthcare management.

These patients, in general, also had psychiatric and other medical comorbidities. The reasons for the higher cost of psychiatric and other medication are not clear. Physicians who use alcoholism pharmacotherapies may be more familiar with appropriate diagnosis and treatment of concurrent psychiatric and medical conditions. Also, because the any medication group spent less time in the hospital, effective outpatient management may have necessitated more aggressive use of outpatient medications.

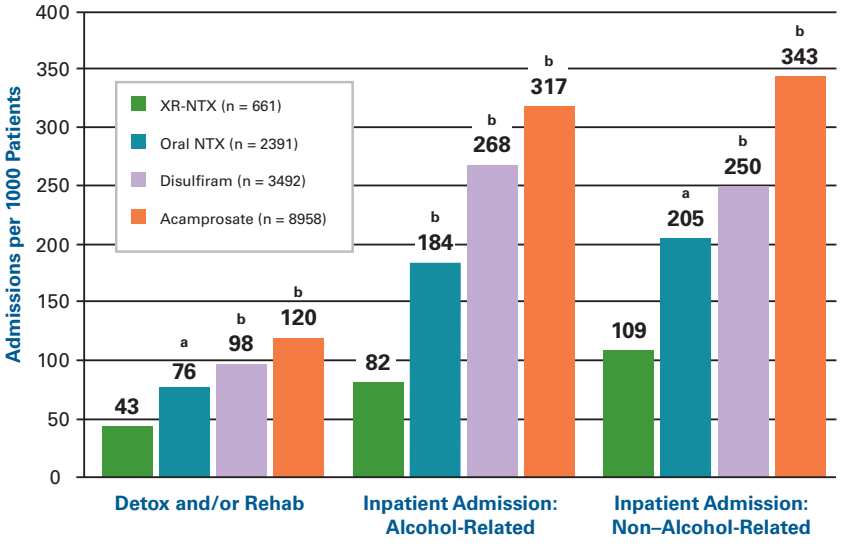
Retrospective claims analyses such as these have a number of limitations. Because the study design did not include random assignment to the any versus no medication conditions, nor to specific medication conditions, the findings represent associations, but not necessarily causality. The cohorts may have had unobserved differences in baseline characteristics; for example, patient motivation or healthcare service quality (eg, physician knowledge and training, psychosocial treatment methods used), so that the precise contribution of medication or type of medication cannot be definitively determined. Because there were no quantitative measures of baseline alcohol use, comparability of the participants' alcohol-use disorder severity across treatment conditions could not be ensured. Similarly, the absence of these baseline data make it impossible to compare reduction in alcohol quantity or frequency across conditions, a commonly used outcome measure in treatment outcome research. No data

**Figure 2.** Alcohol Dependence Pharmacotherapies: Health Economic Outcomes 6 Months After Index Date

**A.** Persistence Days on Medication




**B.** Inpatient Admissions per 1000 Patients




NTX indicates naltrexone; XR-NTX, extended-release injectable naltrexone.
[a] $P < .01$ vs XR-NTX.
[b] $P < .001$ vs XR-NTX.

are available regarding adverse events, which are important considerations, given that medications are known to have side effects, some of which are associated with boxed warnings on the prescribing information, and these differ between the oral and the injectable agents. Also, the time frame for outcomes was limited to 6 months and the samples consisted of commercial insureds as opposed to Medicaid or uninsured patients. Furthermore, the XR-NTX sample was smaller than the others (because it is the most recently introduced agent), subject inclusion was limited to patients with 1 year of continuous enrollment (which could omit those who lost insurance due to job loss), no information was available as to the recommended or adequate duration of treatment, and oral medication adherence was only indirectly measured through

prescription refills (therefore no information was available to confirm that patients took their oral medications).

Despite these limitations, the study has some relevant strengths. Baseline data (Table 2), with propensity-score matching and inverse probability weighting across a number of demographic, clinical, and utilization variables, demonstrated good comparability between the any versus no medication cohorts. The analysis showed robust findings in healthcare cost and utilization domains, a major strength that mitigates the limitation of not having alcohol consumption data. Although the average treatment duration was 2 to 3 months, meaningful outcomes were detected over a 6-month time frame, indicating that treatment benefits may outlast the active treatment phase. The patterns observed with medication adherence, hospital utilization, and costs demonstrated a high degree of internal consistency. External validity was also strong, given the relatively large sample sizes composed of real-world patients treated by community providers and given conventional treatment.

These findings are compatible with real-world evaluations of alcohol pharmacotherapy refill persistence.[12-14,17] Three prior analyses of pharmacy claims for oral NTX refills have shown that as few as half of patients obtain the first refill, and most do not complete a reasonable course of treatment.[12-14] One of these studies found significantly lower refill rates for oral alcohol pharmacotherapies than for statins, antidepressants, and antipsychotics,[14] and another found that refill failure was associated with significantly more detoxifications and hospital admissions.[13]

More recently, a retrospective claims analysis in NJ Blue Cross Blue Shield insureds found that although medication persistence remains an issue, XR-NTX was associated with significant reductions in cost due to alcohol-related hospitalizations, total medical costs, and total pharmacy costs (see the article by Jan et al in this supplement).[32] A study of AETNA beneficiaries showed that patients given XR-NTX persisted with treatment longer than those given oral medications, and XR-NTX was associated with decreased inpatient and emergency healthcare costs and utilization to a greater extent than patients receiving 1 of the 3 oral agents (see the article by Bryson et al in this supplement).[33]

Mark et al also analyzed retrospective commercial claims between any versus no medication, and among the 4 FDA-approved alcoholism medications. They determined that medication was associated with less detoxification and alcoholism-related inpatient care. That study also showed a similar pattern among the 4 medications; increased burden of medication administration (acamprosate >oral NTX or disulfiram >XR-NTX) was associated with decreased refill persistence. The XR-NTX cohort used 224 detoxification days per 1000 patients (vs 227 in the present study) and was associated with the fewest days for detoxification or alcohol-related hospitalizations among the 4 agents.[18] The present study replicates those findings and extends them, because the earlier study consisted of a single data source (examining 5954 matched cases in the any vs no medication comparison and 295 patients given XR-NTX) and used estimated charges and calculated these for only detoxification and alcohol-related inpatient admissions, whereas the present study combined 2 large data sources (examining 20,752 overall cases and 661 patients given XR-NTX) and calculated actual expended dollars for all healthcare costs, including the costs of the agents.

The relationships between use of medications, counseling, and utilization/cost outcomes suggested in these data are intriguing and raise important questions for further research. Although this study confined its cost evaluation to healthcare expenditures, society bears additional costs from alcohol dependence, due to deterioration, absenteeism and loss in the workforce, damage to property and life, and court proceedings and incarceration in the justice system. These costs are worthy of future analysis as well. Effectiveness findings with medication-assisted treatment that takes these aggregate burdens into account have led to implementation strategies in the public sector.[34] The National Quality Forum issued a statement in 2007 that "pharmacotherapy should be a standard component of treatment for SUD [substance use disorders]" [35] and efforts to increase pharmacotherapy use and design performance measures are under way.[36] Effective treatment with medication, and particularly the most effective pharmacologic therapy, is an opportunity that continues to warrant research, education, and implementation initiatives from healthcare systems, insurers, and policymakers.

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***Authorship information:*** Concept and design (MC, RR, DRG); acquisition of data (OB); analysis and interpretation of data (OB, MC, RR, DRG); drafting of the manuscript (OB, MC, RR, DRG); critical revision of the manuscript for important intellectual content (MC, RR, DRG); statistical analysis (OB); obtaining funding (DRG); and administrative, technical, or logistic support (DRG).

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# Cost and Utilization Outcomes of Opioid-Dependence Treatments

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## Abstract

**Objectives:** To evaluate the healthcare costs associated with treatment of opioid-dependence disorder with medications versus no medication, and with the 4 agents approved by the US Food and Drug Administration (FDA).

**Study Design:** Retrospective claims database analysis.

**Methods:** Eligible adults with opioid dependence were identified from a large US health plan and the PharMetrics Integrated Database. Data included all medical and pharmacy claims at all available healthcare sites. Case-mix adjustment was applied using baseline demographic, clinical, and healthcare utilization variables for 13,316 patients; half of these patients used an FDA-approved medication for opioid dependence. A similar comparison was performed among 10,513 patients treated with extended-release naltrexone (NTX-XR) (n = 156) prior to FDA approval for opioid dependence or with a medication approved at the time: oral naltrexone (NTX) (n = 845), buprenorphine (n = 7596), or methadone (n = 1916). Analyses calculated 6-month persistence, utilization, and paid claims for opioid-dependence medications, detoxification and rehabilitation, opioid-related and non-related inpatient admissions, outpatient services, and total costs.

**Results:** Medication was associated with fewer inpatient admissions of all types. Despite higher costs for medications, total healthcare costs, including inpatient, outpatient, and pharmacy costs, were 29% lower for patients who received a medication for opioid dependence versus patients treated without medication. Patients given XR-NTX had fewer opioid-related and non–opioid-related hospitalizations than patients receiving oral medications. Despite higher costs for XR-NTX, total healthcare costs were not significantly different from those for oral NTX or buprenorphine, and were 49% lower than those for methadone.

**Conclusion:** Patients with opioid dependence who received medication for this disorder had lower hospital utilization and total costs than patients who did not receive pharmacologic therapy. Patients who received XR-NTX had lower inpatient healthcare utilization at comparable or lower total costs than those receiving oral medications.

*(Am J Manag Care. 2011;17:S235-S248)*


For author information and disclosures, see end of text.

Opioid-dependence disorder, or addiction, is a complex brain disease characterized by "uncontrollable drug craving, along with compulsive drug seeking and use that persist even in the face of devastating consequences."[1] In 2009, there were over 2 million opioid-dependent adults in the United States[2] and prescription opioid dependence has been increasing over the last 20 years due to growth in prescribing of high potency opioids for the treatment of pain. Drug overdose deaths now surpass gunshot deaths; in 16 states overdose deaths are more common than lethal car crashes, and drugged driving occurs at higher levels than alcohol-impaired driving.[3] Among those dependent upon heroin, it is estimated that more than 18 years of potential life are lost by age 65, with the leading causes of death being overdose, chronic liver disease, and accidents.[4] The cost of heroin dependence in the United States was estimated at $21 billion in 2000.[5]



There are 3 main classes of oral pharmacologic treatments for opioid dependence: opioid receptor agonists (methadone),[6] partial agonists (buprenorphine, buprenorphine/naloxone),[7] and antagonists (oral naltrexone [NTX]).[8] Agonist therapy is effective for a broad range of dependence consequences and outcomes, although diversion and abuse can be problematic.[9] Antagonist therapy (ie, oral NTX) is not abused; however, its clinical effectiveness has been limited by poor patient compliance with daily dosing,[10] leading the National Institute on Drug Abuse to call for a sustained-release antagonist preparation.[11] Extended-release naltrexone (XR-NTX)[12] was approved by the US Food and Drug Administration (FDA) in October 2010 for the treatment of alcohol dependence and the prevention of relapse to opioid dependence following detoxification.

Much of the population with opioid dependence remains untreated, due to obstacles including denial about the disease, poor motivation, stigma, limited insurance coverage, and limited access to care; factors that have been proposed to improve this situation include expanded access to opioid agonist treatment, treatment with a nonreinforcing "blocker," treatment in a conventional medical setting, and an approach that conforms to the abstinence model.[3,13-16]

Given the growing health and social burdens of opioid dependence and new formulations and approaches to treatment introduced in the past 10 years, the present study was designed to examine a comprehensive range of real-world healthcare costs and

utilization with available treatments, including treatment with no medication, treatment with any of the currently approved medications, and among the currently approved medications, treatment with each of the 4 agents.

## Methods

### *Data Sources and Study Population*

Health Insurance Portability and Accountability Act–compliant pharmacy and medical administrative claims data from a proprietary US health plan and the PharMetrics Integrated Database for calendar years 2005 through 2009 were used for this retrospective, longitudinal study. For the first source, data for approximately 14 million individuals was available in 2008. The PharMetrics Integrated Database includes 85 US health plans providing healthcare coverage to more than 10 million persons annually throughout the United States. These data sources are well validated and were chosen because they cover large numbers of patients across all parts of the United States.

The end points of the study were healthcare cost and utilization. Two different comparisons were conducted: (1) between treated patients with any medication versus no medication, and (2) among patients treated with medication, comparison of patients treated with (a) XR-NTX; (b) oral NTX; (c) buprenorphine (with or without naloxone); and (d) methadone. Patients treated with XR-NTX were identified on the basis of an outpatient drug claim from the National Drug Code (NDC) or medical claims from the Healthcare Common Procedure Coding System code (because it is the 1 agent administered with a procedure). The other medications were identified using outpatient drug claims based on NDCs.

For patients in the no medication group, the index date was defined as the first medical claim for a nonpharmacologic treatment, such as a detoxification facility claim, a substance abuse treatment facility claim, or a substance abuse counseling claim. The index date for the group with medication use was determined as the earliest pharmacy claim for opioid medication.

The database's study population included patients continuously enrolled in a commercial health plan for at least 1 year (6 months pre–index date and 6 months post–index date). Patients were required to have at least 1 claim for opioid dependence or opioid-use disorder (*International Classification of Diseases, 9th Revision, Clinical Modification* [*ICD-9-CM*] codes 304.0x, 304.7x) in the 6 months prior to the index date or on the index date. Patients were excluded from the analysis if they (1) had claims for pharmacologic treatment for opioid dependence in the 1 month prior to the index date for patients with claims for oral NTX, buprenorphine, methadone, or nonpharmacologic treatment on the index date; or (2) had claims with a diagnosis of acute hepatitis or liver failure in the 6 months pre-index. This later restriction was applied due to the varying hepatic safety profiles of the medications.[17-19] **Figure 1** details the patient cohorts.

### *Study Variables*

Patients' age, sex, and geographic region were determined from the claims record. Using a previously validated formula for socioeconomic status,[20] we constructed a summary measure of socioeconomic status for each US Zone Improvement Plan (ZIP) code using data on income, education, and occupation from the 2000 US Census, and then linked this information to the patients' ZIP code of residence in the analytic files.[21] Comorbid conditions were measured during the 6-month period before the index date and defined using the methods of Elixhauser[22] and Charlson[23] to produce a single score for use in multivariate models. The Deyo-Charlson comorbidity score is an *ICD-9* code adaption of the Charlson index, which assigns a range of weights, from 1 to 6 according to disease severity, for 19 conditions. The Elixhauser score is also a claims-based comorbidity index which sums a patient's comorbid conditions from among 30 *ICD-9-CM* comorbidity flags, differentiating secondary diagnoses from comorbidities by using diagnosis-related groups.

Costs were calculated using the actual patient claims for healthcare use in the matched cohort. They are measured during both the pre- and post-index periods. In addition to the overall costs, the costs of detoxification and/or rehabilitation visits, opioid- and non–opioid-related inpatient and outpatient visits and emergency department (ED) visits, opioid-related physician visits, and opioid and substance abuse psychosocial provider visits were calculated.

Healthcare utilizations are represented per 1000 patients and detailed similar to healthcare costs. Adherence and persistence were measured using medication possession ratio (MPR) and time from the index date until time of discontinuation. MPR was calculated as the ratio of days' supply of the index medication to total days in the observation period and it was corrected for inpatient events under the assumption that during hospitalization, medication is supplied by the facility. The date of discontinuation was defined by the run-out days supply of the last prescription filled prior to the gap in therapy.

### *Analyses*

Baseline characteristics were compared between patient cohorts and descriptive statistics were calculated as mean

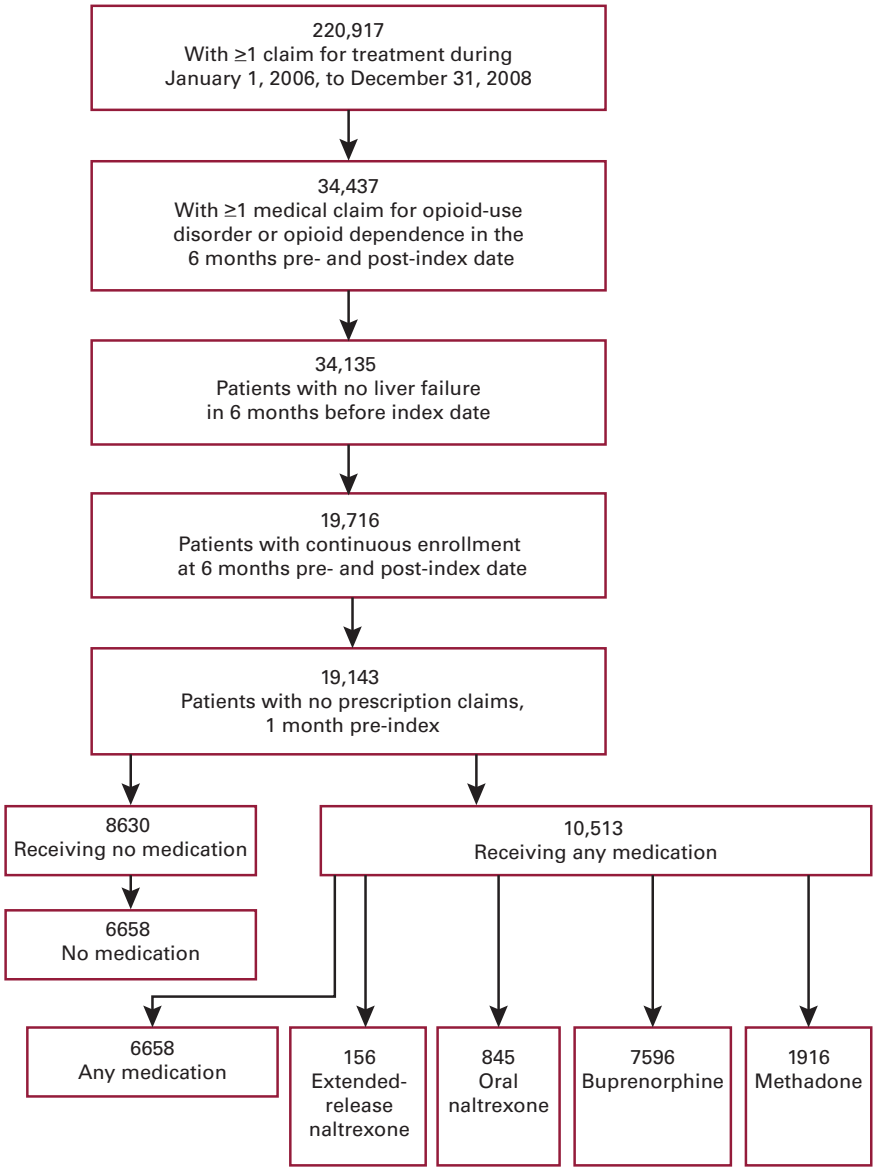
(standard deviation) and percentages. Differences between the cohorts were analyzed using the *t*-test, Mann-Whitney U tests, and $\chi^2$ tests.

A challenge to retrospective cohort studies in general—and to this study in particular—is the question of comparability of patient groups at the time of treatment initiation (ie, is the physician equally likely to choose between the treatment options, or rather is the choice of treatment based on patient profile?). Differences in patient and provider characteristics that influence choice of treatment can confound healthcare utilization and costs, especially when one of the treatments is used off label. One method to adjust for differences in patient profiles is propensity-score analysis.[24-26] Heckman et al argued convincingly that if patients are matched using the propensity score, up to 85% of the bias resulting from unequal distributions in patient characteristics can be removed.[27]

Propensity-score analysis can be implemented in a variety of ways. For medication and nonmedication cohorts we used a logistic regression model to predict the probability that patients belong in each group on the basis of their observed characteristics. The model covariates consisted of age, sex, region, and socioeconomic status variables, baseline healthcare comorbidities, utilization, and costs.

Once each patient was assigned a propensity score, patients in the medication cohort were matched with the pool of patients in the nonmedication cohort. Matching was undertaken using nearest neighbor 1:1 matching and the resulting matched cohort was compared to determine whether balanced cohorts were created.[28] Statistical analyses were performed using SAS v9.2 (SAS Institute, Cary, North Carolina) and STATA v10 (Stata Corp, College Station, Texas).

**Figure 1.** Patient Selection Process




For treatment types in the medication cohort, to further control for unobserved biases, the instrumental variable (IV) approach was used. One of the limitations of propensity-score matching analyses is that they control for observed bias (ie, selection from observed and measured factors) but not for unobserved bias. The IV approach is a technique that can be used to control for both observed and unobserved sources of bias, and to ascertain whether the results from the more standard approaches (propensity-score matching or multivariate regression) diverge from the IV results.

An instrument is a variable that does not belong in the explanatory equation and is correlated with the endogenous

**Table 1.** Baseline Characteristics of Opioid-Dependent Patients With and Without Any Medication

| Post-Index Period (6 months after index date) | Opioid-Dependence Treatment: Any Medication (N = 10,513) | Opioid-Dependence Treatment: No Medication (N = 8630) | |
|---|---|---|---|
| **Continuous variables** | **Mean (SD)** | **Mean (SD)** | ***P*** |
| Pre-index Deyo-Charlson comorbidity score | 0.35 (0.98) | 0.33 (0.95) | .1489 |
| Pre-index Elixhauser comorbid conditions | 1.56 (1.65) | 1.27 (1.61) | **<.0001** |
| Pre-index number of distinct psychiatric diagnoses | 2.56 (1.78) | 2.25 (1.85) | **<.0001** |
| Pre-index number of distinct psychiatric medications | 2.25 (2.04) | 1.61 (1.90) | **<.0001** |
| **Healthcare utilization** | | | |
| Pre-index number of detoxification facility days (number of days/1000 patients) | 1092 (3110) | 109 (1786) | **<.0001** |
| Pre-index inpatient (number of admissions/1000 patients) | | | |
| Detoxification and/or rehabilitation | 195 (462) | 16 (201) | **<.0001** |
| Opioid-related inpatient admission | 221 (523) | 48 (255) | **<.0001** |
| Non–opioid-related inpatient admission | 384 (884) | 277 (811) | **<.0001** |
| Pre-index outpatient (number of visits/1000 patients) | | | |
| Emergency department visits | 1410 (4241) | 1107 (3491) | **<.0001** |
| Opioid-related and physician provider | 266 (1795) | 105 (1080) | **<.0001** |
| Opioid-related and substance abuse psychosocial provider | 117 (1154) | 93 (1184) | .1471 |
| Non–opioid-related outpatient | 14,152 (16,098) | 12,951 (15,279) | **<.0001** |
| **Costs (per patient)** | | | |
| **Pre-index inpatient** | | | |
| Cost of detoxification and/or rehabilitation | $430 ($1497) | $0 ($0) | **<.0001** |
| Cost of opioid-related inpatient admission | $665 ($2768) | $156 ($1513) | **<.0001** |
| Cost of non–opioid-related inpatient admission | $4581 ($29,587) | $2689 ($16,097) | **<.0001** |
| **Pre-index outpatient** | | | |
| Cost of emergency department visits | $4450 ($1484) | $328 ($1326) | **<.0001** |
| Cost of opioid-related and physician provider | $28 ($292) | $9 ($202) | **<.0001** |
| Cost of opioid-related and substance abuse psychosocial provider | $14 ($175) | $6 ($116) | **.0002** |
| Cost of non–opioid-related | $30 ($42) | $26 ($35) | **<.0001** |
| **Pre-index pharmacy** | **Mean (SD)** | **Mean (SD)** | ***P*** |
| Cost of FDA-approved opioid-dependence medications | $2 ($53) | $0 ($0) | **<.0001** |
| Cost of other psychiatric medications | $176 ($531) | $77 ($366) | **<.0001** |
| Cost of nonpsychiatric medications | $913 ($2757) | $380 ($1865) | **<.0001** |
| **Total cost (including inpatient, outpatient, and pharmacy)** | **$10,710 ($34,138)** | **$6791 ($18,916)** | **<.0001** |

FDA indicates US Food and Drug Administration.

explanatory variables, conditional on the other covariates. In this study, because XR-NTX was not yet approved for the opioid dependence treatment indication (and was therefore being utilized off label), its use often required unique physician considerations and reimbursement processes resulting in unique cohort characteristics. Therefore, due to a high probability that unobserved bias would play a role in the use of this agent, copayment and physician/provider prescribing patterns derived from the claims and provider-level data served as instruments. The variables were tested to determine whether they were strong or weak instruments. From prior experience, it is known that physicians' prescribing patterns are very strong instruments because they are strongly related to treatment choices.

## Results

Table 1 reports the baseline demographic and clinical characteristics of the sample, stratified by the any medication and no medication groups. Patients were similar in terms of age (36.2 years vs 36.2, respectively; *P* = NS) and sex (61.5% male vs 60.3%, respectively; *P* = NS). Patients in the any medication cohort were less likely to be from the South

**Table 2.** Risk-Adjusted Outcomes in Opioid-Dependent Patients With and Without Any Medication

| Post-index period (6 months after index date) | Opioid-Dependence Treatment: Any Medication (N = 6658) | Opioid-Dependence Treatment: No Medication (N = 6658) | |
|---|---|---|---|
| **Outcome** | **Mean (SD)** | **Mean (SD)** | ***P*** |
| Post-index number of distinct psychiatric diagnoses | 3.01 (1.70) | 3.81 (2.14) | **<.0001** |
| Post-index number of distinct psychiatric medications | 2.49 (2.14) | 1.91 (2.05) | **<.0001** |
| **Healthcare utilization** | | | |
| Post-index number of detoxification facility days (number of days/1000 patients) | 447 (2250) | 4758 (7840) | **<.0001** |
| **Post-index inpatient (number of admissions/1000 patients)** | | | |
| Detoxification and/or rehabilitation | 74 (317) | 770 (721) | **<.0001** |
| Opioid-related inpatient admission | 111 (407) | 677 (811) | **<.0001** |
| Non–opioid-related inpatient admission | 292 (787) | 731 (1417) | **<.0001** |
| **Post-index outpatient (number of visits/1000 patients)** | | | |
| Emergency department visits | 1084 (3090) | 1041 (3125) | **.0372** |
| Opioid-related and physician provider | 1104 (3941) | 776 (3724) | **<.0001** |
| Opioid-related and substance abuse psychosocial provider | 301 (2054) | 553 (3196) | **<.0001** |
| Non–opioid-related outpatient | 17,389 (17,147) | 17,119 (17,663) | .1185 |
| **Costs (per patient)** | | | |
| **Post-index inpatient** | | | |
| Cost of detoxification and/or rehabilitation | $205 ($1240) | $2083 ($3434) | **<.0001** |
| Cost of opioid-related inpatient admission | $381 ($2299) | $1823 ($4800) | **<.0001** |
| Cost of non–opioid-related inpatient admission | $2928 ($15,420) | $4184 ($21,621) | **<.0001** |
| **Post-index outpatient** | | | |
| Cost of emergency department visit | $357 ($1211) | $288 ($1182) | **<.0001** |
| Cost of opioid-related and physician provider | $115 ($565) | $91 ($550) | **<.0001** |
| Cost of opioid-related substance abuse psychosocial provider | $25 ($213) | $47 ($361) | **<.0001** |
| Cost of non–opioid-related | $35 ($40) | $323 ($40) | **.0002** |
| **Post-index pharmacy** | | | |
| Cost of FDA-approved opioid-dependence medications | $1078 ($1256) | $1 ($41) | **<.0001** |
| Cost of other psychiatric medications | $278 ($755) | $132 ($498) | **<.0001** |
| Cost of nonpsychiatric medications | $851 ($2158) | $357 ($1169) | **<.0001** |
| **Total cost per patient (including inpatient, outpatient, and pharmacy)** | $10,192 ($19,472) | $14,353 ($25,780) | **<.0001** |

FDA indicates US Food and Drug Administration.

(18.5%) than patients in the no medication cohort (33.4%; *P* <.0001), and a smaller percentage had socioeconomic status scores in the bottom third (27.6%) relative to patients in the no medication cohort (39.8%; *P* <.0001).

As expected, given the possibilities for adverse selection, patients in the any medication cohort appeared to be sicker than those in the no medication cohort, both medically, with more having an Elixhauser comorbidity score of 3 or greater (22.9% vs 18.4%, respectively; *P* <.0001), and psychiatrically, with more having psychiatric diagnoses and taking psychiatric medications (*P* <.001 for all comparisons).

In terms of healthcare utilization, the 6 month pre-index utilization was higher in the any medication group, including number of detoxification facility days, detoxification and/or rehabilitation admissions, opioid-related and non–opioid-related inpatient and outpatient admissions, ED visits, and opioid-related provider visits.

This greater utilization in the any medication group translated into higher healthcare costs relative to the no medication group. Compared with patients not receiving medication, all of the inpatient and outpatient costs were significantly higher in those receiving medication. The

**Table 3.** Baseline Characteristics in Opioid-Dependent Patients by Pharmacotherapy

| Pre-Index Period | Opioid Dependence Medication | | | | | | |
|---|---|---|---|---|---|---|---|
| | XR-NTX (n = 156) | Oral NTX (n = 845) | | Buprenorphine (n = 7596) | | Methadone (n = 1916) | |
| **Patient characteristics** | **n (%)** | **n (%)** | ***P*** | **n (%)** | ***P*** | **n (%)** | ***P*** |
| Pre-index severity (Elixhauser ≥3) | 53 (34.0%) | 293 (34.7%) | .8658 | 1421 (18.1%) | **<.0001** | 635 (33.1%) | .8319 |
| **Continuous variables** | **Mean** | **Mean** | ***P*** | **Mean** | ***P*** | **Mean** | ***P*** |
| **Clinical characteristics** | | | | | | | |
| Pre-index Deyo-Charlson comorbidity score | 0.22 (0.67) | 0.24 (0.66) | .7494 | 0.26 (0.79) | .4480 | 0.77 (1.55) | **<.0001** |
| Pre-index Elixhauser comorbid conditions | 2.06 (1.75) | 2.05 (1.67) | .9304 | 1.37 (1.49) | **<.0001** | 2.05 (2.04) | .9105 |
| Pre-index number of distinct psychiatric diagnoses | 3.76 (2.06) | 3.78 (2.29) | .8825 | 2.48 (1.67) | **<.0001** | 2.23 (1.69) | **<.0001** |
| Pre-index number of distinct psychiatric medications | 2.70 (2.72) | 2.48 (2.27) | .3518 | 2.12 (1.90) | **.0086** | 2.62 (2.31) | .7277 |
| **Healthcare utilization** | | | | | | | |
| Pre-index number of detoxification facility days (number of days/1000 patients) | 2391 (5486) | 1782 (3474) | .1828 | 1188 (3201) | **.0071** | 301 (1918) | **<.0001** |
| **Pre-index inpatient (number of admissions/1000 patients)** | | | | | | | |
| Detoxification and/or rehabilitation | 353 (660) | 336 (568) | .7705 | 212 (475) | **.0091** | 53 (261) | **<.0001** |
| Opioid-related inpatient admission | 282 (1418) | 351 (583) | .5478 | 237 (509) | .6913 | 95 (368) | .1023 |
| Non–opioid-related inpatient admission | 718 (1135) | 680 (1077) | .7029 | 273 (717) | **<.0001** | 668 (1208) | .5999 |
| **Outpatient (number of visits/1000 patients)** | | | | | | | |
| Emergency department visits | 1154 (2717) | 1322 (3701) | .5055 | 1331 (3543) | .4240 | 1781 (6489) | **.0177** |
| Opioid-related and physician provider | 750 (3753) | 328 (1926) | .1718 | 284 (1844) | .1239 | 127 (1181) | **.0405** |
| Opioid-related and substance abuse psychosocial provider | 699 (3880) | 214 (1382) | .1250 | 113 (1109) | .0616 | 43 (576) | **.0366** |
| Non–opioid-related outpatient | 15,494 (14,515) | 14,669 (15,263) | .5184 | 12,125 (14,390) | **.0047** | 21,853 (20,137) | **<.0001** |
| **Costs (per patient)** | | | | | | | |
| **Pre-index inpatient** | | | | | | | |
| Cost of detoxification and/or rehabilitation | $1083 ($2793) | $767 ($1832) | .1754 | $458 ($1538) | **.0060** | $119 ($790) | **<.0001** |
| Cost of opioid-related inpatient admission | $607 ($1994) | $1108 ($3188) | **.0102** | $721 ($2946) | .4859 | $253 ($1598) | **.0320** |
| Cost of non–opioid-related inpatient admission | $3407 ($7753) | $4386 ($13,666) | .2096 | $2412 ($11,495) | .1189 | $13,360 ($64,017) | **<.0001** |
| **Pre-index outpatient** | | | | | | | |
| Cost of emergency department visits | $425 ($1316) | $455 ($1639) | .8049 | $445 ($1321) | .8502 | $467 ($1961) | .7180 |
| Cost of opioid-related and physician provider | $111 ($627) | $50 ($445) | .2449 | $29 ($292) | .1047 | $8 ($98) | **.0431** |
| Cost of opioid-related and substance abuse psychosocial provider | $74 ($567) | $41 ($311) | .4695 | $13 ($156) | .1762 | $4 ($53) | .1212 |
| Cost of non–opioid-related | $30 ($34) | $29 ($35) | .9012 | $26 ($37) | .1353 | $48 ($56) | **<.0001** |
| **Pre-index pharmacy** | | | | | | | |
| Cost of FDA-approved opioid -dependence medications | $157 ($408) | $0 ($0) | **<.0001** | $0 ($0) | **<.0001** | $0 ($0) | **<.0001** |
| Cost of other psychiatric medications | $282 ($722) | $217 ($600) | .2911 | $172 ($520) | .0604 | $164 ($521) | **.0473** |
| Cost of nonpsychiatric medications | $598 ($1285) | $530 ($1295) | .5459 | $845 ($2330) | **.0213** | $1377 ($4362) | **<.0001** |
| **Total cost (including inpatient, outpatient, and pharmacy)** | $10,393 ($12,677) | $11,527 ($17,455) | .3368 | $7,753,216 ($15,868,760) | **.0114** | $22,098 ($71,320) | **<.0001** |

FDA indicates US Food and Drug Administration; NTX, naltrexone; XR-NTX, extended-release injectable naltrexone.

6-month total cost including inpatient, outpatient, and pharmacy costs was $10,710 per patient in the any medication group compared with $6791 per patient in the no medication group.

Using propensity-score matching, 6658 patients from each group were matched. **Table 2** presents the risk-adjusted 6-month outcomes following the index treatment for patients in the any medication and no medication groups. Patients in the any medication group had fewer psychiatric diagnoses (3.01 vs 3.81), but more frequent use of distinct psychiatric medications (2.49 vs 1.91) relative to patients in the no medication group. Compared with patients in the no medication group, the number of detoxification facility days was significantly lower for patients in the any medication group (4758 vs 447 per 1000 patients). Post-index detoxification and/or rehabilitation admissions (74 vs 770) and opioid-related (111 vs 677) and non–opioid-related (292 vs 731) admissions were significantly lower per 1000 patients in the any medication group compared with the no medication group. Fewer inpatient admissions translated into lower inpatient costs in the any medication group. In particular, the 6-month costs per patient among those receiving medication for detoxification and/or rehabilitation admissions ($205 vs $2083) and opioid-related ($381 vs $1823) and non–opioid-related ($2928 vs $4184) admissions were significantly lower compared with those not receiving medication.

The pattern of healthcare utilization and cost for outpatient services was more mixed, with significantly higher use and cost associated with some categories of outpatient services in the any medication group. Overall healthcare cost savings, however, were $4161 per patient treated with medication relative to those not receiving medication ($10,192 vs $14,353).

Out of 10,513 patients who were given medication, 156 (1.5%) patients were treated with XR-NTX, 845 (8.3%) with oral NTX, 7596 (72%) with buprenorphine, and 1916 (18.2%) with methadone. Patients in the XR-NTX group were more likely to be male (75% vs 58.7%, 64.1%, and 51.4%, respectively; all $P$ <.01) and tended to reside in the eastern part of the United States relative to the other groups (37.8% vs 30.2%, $P$ = .06; 30.4%, $P$ <.05; and 14.2%, $P$ <.0001, respectively). They were older (36.9 years) compared with patients who received oral NTX (34.2; $P$ = .02) or buprenorphine (34.8; $P$ = .06), but younger relative to methadone users (42.3%; $P$ <.0001). The XR-NTX group had significantly fewer patients with the lowest socioeconomic score relative to all 3 oral medication groups (18.6% vs 31.7%, 26.0%, and 32.9%, respectively; all $P$ <.05).

Patient pre-index clinical characteristics in the 4 opioid medication groups are presented in **Table 3**. Although the distribution was similar among the other groups, patients given buprenorphine appeared to be healthier at the baseline, with significantly fewer patients with an Elixhauser index score of 3 or greater, and fewer distinct psychiatric diagnoses and medications.

Patients in the XR-NTX cohort spent significantly more days in a detoxification facility (2391 per 1000 patients) relative to those in the buprenorphine (1188) and methadone (301) cohorts. Similarly, the number of patients admitted to detoxification and/or rehabilitation centers at baseline was greater for those given XR-NTX (353) versus those given buprenorphine (212) and methadone (53). This translated into a higher cost for detoxification and rehabilitation at baseline in patients receiving XR-NTX. Outpatient resource use and cost were similar among the groups at baseline, excepting significantly greater opioid-related outpatient physician visits and costs and significantly less non–opioid-related outpatient visits and costs in the XR-NTX group compared with the methadone group.

Total healthcare cost during the 6-month pre-index period for patients in the XR-NTX group was significantly higher versus the buprenorphine group, but lower versus the methadone group. Among opioid-dependent patients at baseline, there were no significant differences in costs between the XR-NTX and oral NTX groups.

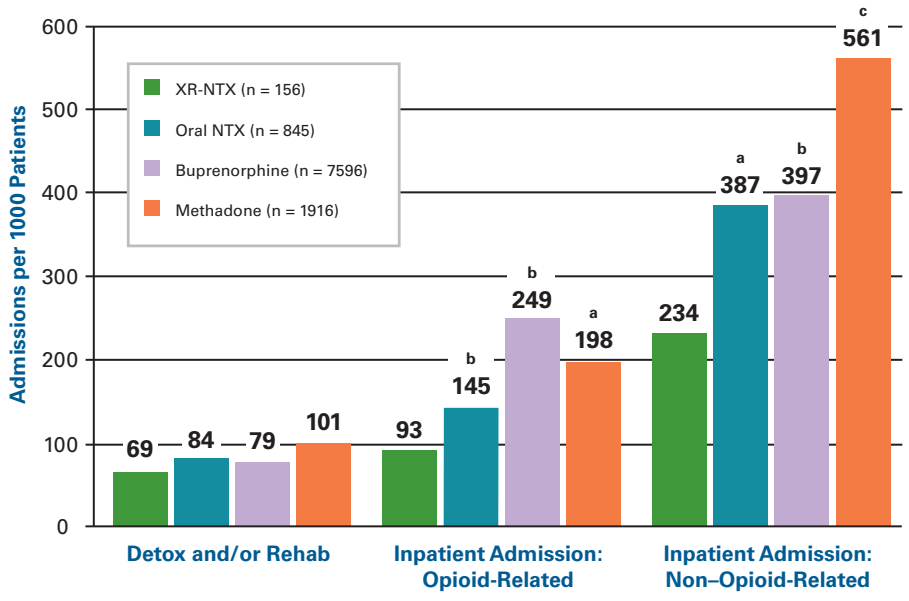
Overall, the XR-NTX group showed notable cohort differences, including a greater percentage of patients who were male, were from the eastern United States, had higher socioeconomic status, and had higher utilization rates for physician services and detoxification. This pattern indicated a substantial degree of prescribing bias, consistent with the fact that XR-NTX was not yet approved by the FDA for the prevention of relapse to opioid dependence following detoxification. Baseline differences among the opioid treatment groups were controlled using the instrumental variable approach; risk-adjusted outcomes are presented in **Figure 2** and **Table 4**.

Compared with patients given oral NTX, those given XR-NTX had a greater number of refill persistence days (55 vs 61 days, respectively), fewer distinct psychiatric medications (2.34 vs 1.99, respectively), fewer detoxification days (71 vs 62 per 1000 patients, respectively), fewer detoxification or rehabilitation admissions (84 vs 69, respectively), fewer ED visits (767 vs 608, respectively), and significantly fewer opioid-related inpatient admission rates (145 vs 93, respectively) and non–opioid-related inpatient admission rates (387 vs 234, respectively) (Figure 2A).

The overall healthcare costs for patients given XR-NTX were not different from those given buprenorphine,

**Figure 2.** Opioid-Dependence Pharmacotherapies: Health Economic Outcomes 6 Months After Index Date

**A.** Inpatient Admissions per 1000 Patients:
Instrumental Variable Matched Outcomes 6 Months After Index Date




**B.** Inpatient Costs per Patient:
Instrumental Variable Matched Outcomes 6 Months After Index Date

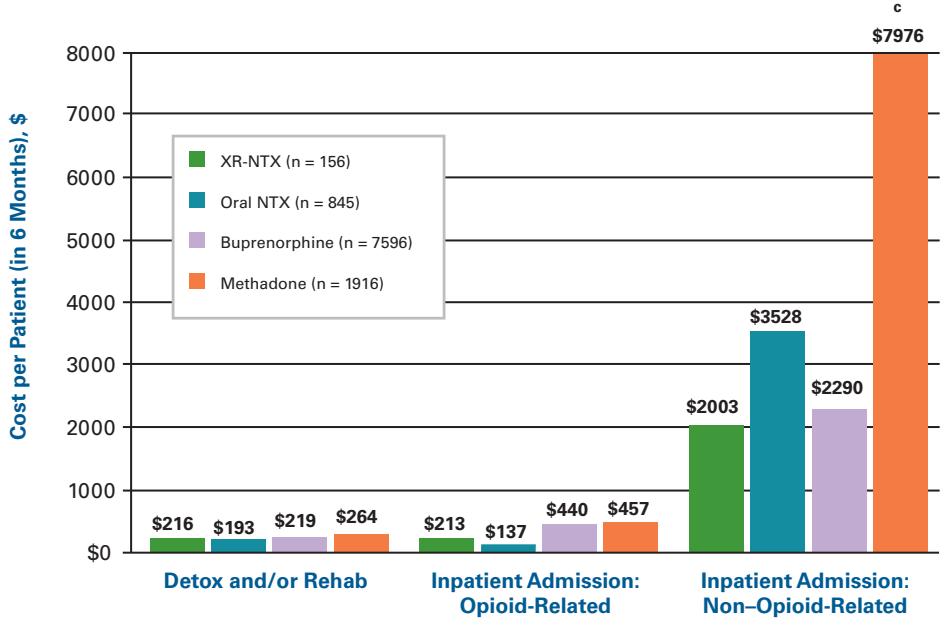
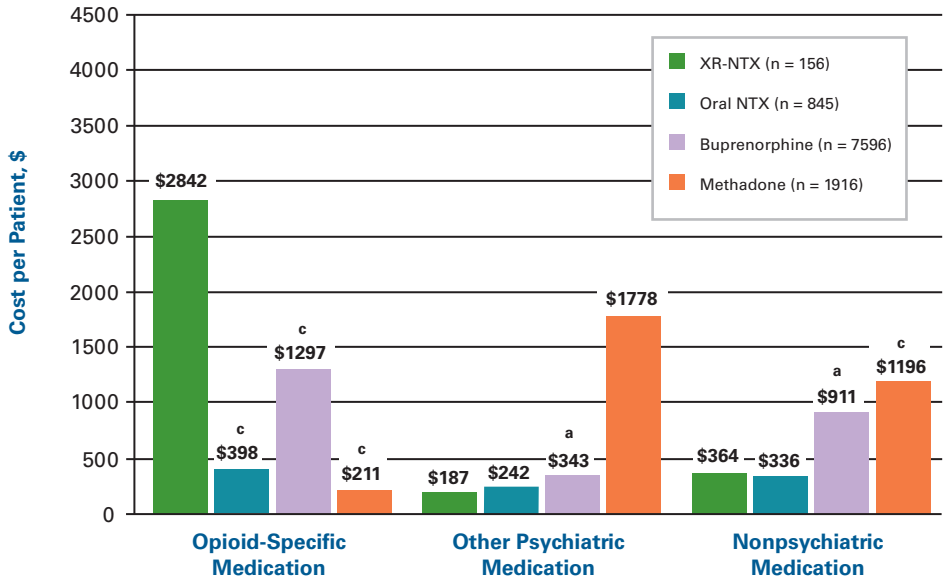
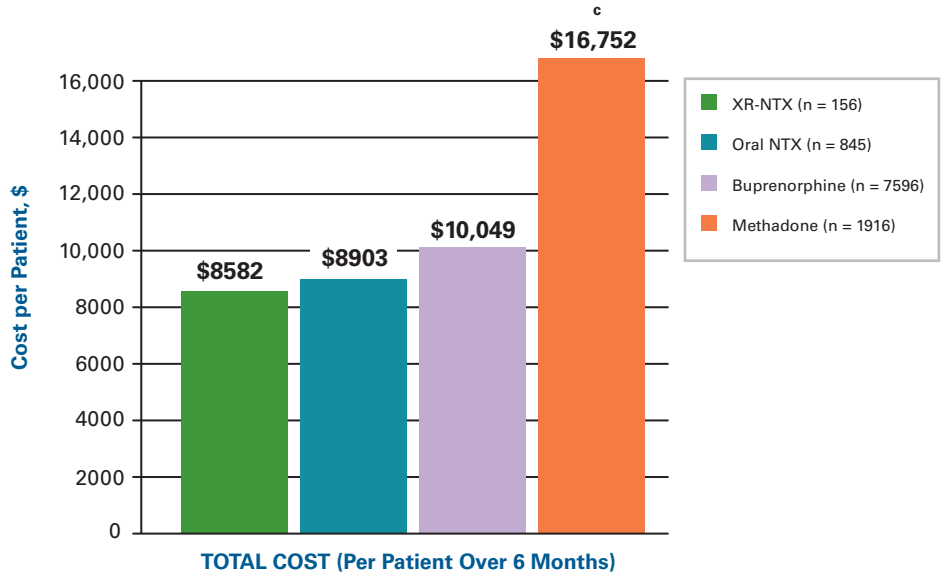


**Figure 2.** Opioid-Dependence Pharmacotherapies: Health Economic Outcomes 6 Months After Index Date *(Continued)*

**C.** Pharmacy Costs per Patient:
Instrumental Variable Matched Outcomes 6 Months After Index Date




**D.** Total Cost per Patient (inpatient + outpatient + pharmacy costs):
Instrumental Variable Matched Outcomes 6 Months After Index Date




NTX indicates naltrexone; XR-NTX, extended-release injectable naltrexone.
*P* vs XR-NTX:
[a] *P* <.05.
[b] *P* <.01.
[c] *P* <.001.

**Table 4.** Risk-Adjusted Outcomes Measures in Opioid-Dependent Patients by Pharmacotherapy

| Post-Index Period | Opioid Dependence Medication | | | | | | |
|---|---|---|---|---|---|---|---|
| | XR-NTX (n = 156) | Oral NTX (n = 845) | | Buprenorphine (n = 7596) | | Methadone (n = 1916) | |
| **Compliance and persistence with therapy** | % | % | *P* | % | *P* | % | *P* |
| Continuous MPR ≥0.8 | 21 | 8 | **<.0001** | 34 | **.0105** | 29 | .0959 |
| **Outcome** | Mean | Mean | *P* | Mean | *P* | Mean | *P* |
| Persistence days with index medication | 61.49 | 54.98 | .229 | 68.92 | 0.142 | 62.8 | .798 |
| Post-index number of distinct psychiatric diagnoses | 3.52 | 3.47 | .727 | 3.12 | **.004** | 2.7 | **<.0001** |
| Post-index number of distinct psychiatric medications | 1.99 | 2.34 | .062 | 2.59 | **.001** | 2.72 | **<.0001** |
| **Healthcare utilization** | | | | | | | |
| Post-index number of detoxification facility visits (number of visits/1000 patients) | 62 | 71 | .672 | 66 | .851 | 82 | .333 |
| **Post-index inpatient (number of admissions/1000 patients)** | | | | | | | |
| Detoxification and/or rehabilitation | 69 | 84 | .61 | 79 | .704 | 101 | .243 |
| Opioid-related inpatient admission | 93 | 145 | **.005** | 249 | **.007** | 198 | **.025** |
| Non–opioid-related inpatient admission | 234 | 387 | **.027** | 397 | **.001** | 561 | **<.0001** |
| **Post-index outpatient (number of visits/1000 patients)** | | | | | | | |
| Emergency department visits | 608 | 767 | .575 | 1092 | .067 | 1590 | **<.0001** |
| Opioid-related and physician provider | 869 | 395 | .173 | 1362 | .13 | 452 | .208 |
| Opioid-related and substance abuse psychosocial provider | 528 | 452 | .705 | 391 | .465 | 241 | .132 |
| Non–opioid-related outpatient | 16,654 | 16,338 | .824 | 16,840 | .889 | 22,054 | **<.0001** |
| **Costs (per patient)** | | | | | | | |
| **Post-index inpatient** | | | | | | | |
| Cost of detoxification and/or rehabilitation | $216 | $193 | .571 | $219 | .721 | $264 | .619 |
| Cost of opioid-related inpatient admission | $213 | $137 | .725 | $440 | .263 | $457 | .235 |
| Cost of non–opioid-related inpatient admission | $2003 | $3528 | .296 | $2290 | .834 | $7976 | **<.0001** |
| **Post-index outpatient** | | | | | | | |
| Cost of emergency department visits | $184 | $283 | .409 | $402 | .051 | $462 | **.014** |
| Cost of opioid-related and physician provider | $95 | $6 | .077 | $150 | .243 | $52 | .37 |
| Cost of opioid-related and substance abuse psychosocial provider | $29 | $267 | .903 | $34 | .782 | $22 | .735 |
| Cost of non–opioid-related | $4510 | $4068 | .248 | $3678 | **.025** | $6173 | **.0005** |
| **Post-index pharmacy** | | | | | | | |
| Cost of FDA-approved opioid-dependence medications | $2842 | $398 | **<.0001** | $1297 | **<.0001** | $211 | **<.0001** |
| Cost of other psychiatric medications | $187 | $242 | .431 | $343 | **.017** | $1778 | .888 |
| Cost of nonpsychiatric medications | $364 | $336 | .904 | $911 | **.014** | $1196 | **<.0001** |
| **Total cost (per patient = inpatient, outpatient, and pharmacy)** | $8582 | $8903 | .867 | $10,049 | .414 | $16,752 | **<.0001** |

FDA indicates US Food and Drug Administration; MPR, medication possession ratio; NTX, naltrexone; XR-NTX, extended-release injectable naltrexone.

despite significantly greater costs for the FDA-approved opioid-dependence medication ($2842 vs $1297, respectively)(Figure 2C). Patients receiving buprenorphine had greater refill persistence than those receiving XR-NTX (69 vs 61 days, respectively), but had significantly more opioid-related inpatient admissions (249 vs 93 per 1000 patients, respectively) (Figure 2A), more non–opioid-related inpatient admissions (397 vs 234, respectively) (Figure 2A), and more ED visits (1092 vs 608, respectively).

Given these overall utilization differences and their related costs, the overall healthcare costs per patient in the group treated with methadone were significantly greater than those with XR-NTX ($16,752 vs $8582, respectively) (Figure 2D), despite the significantly lower cost for the opioid dependence pharmacotherapy ($211 vs $2842, respectively) (Figure 2C). Patients given methadone or XR-NTX showed similar prescription persistence. Compared with patients given XR-NTX, those given methadone had a significantly greater number of distinct psychiatric diagnoses, but lower use of distinct psychiatric medications. Also, patients receiving methadone spent more days in detoxification (82 vs 62 per 1000 patients, respectively), had more detoxification or rehabilitation admissions (101 vs 69, respectively) (Figure 2A), had more opioid-related inpatient admissions (198 vs 93, respectively) (Figure 2A), had significantly more ED visits (1590 vs 608, respectively), and had significantly more non–opioid-related outpatient visits (22,054 vs 16,654, respectively) compared with those receiving XR-NTX.

## Discussion

The combined data from these 2 large insurance data sets made possible the first study to date examining healthcare costs and utilization for the full set of currently available opioid-dependence treatments. This risk-adjusted analysis compared outcomes in 13,316 patients who received any versus no medication for opioid-dependence disorder and 10,513 patients who received 1 of the 4 FDA-approved pharmacologic therapies. Thus, this study was one of the largest health economic studies in this disorder to date, and the first such study to analyze treatment with XR-NTX. The study was a comprehensive analysis of total healthcare costs paid and corresponding healthcare service utilization. Compared with opioid-dependence treatment that did not include medication, medication-assisted treatment was associated with significantly fewer admissions for detoxification and/or rehabilitation, opioid-related inpatient medical care, and non–opioid-related inpatient medical care. In all of these inpatient service categories, costs were significantly lower in patients who received a medication, and total healthcare costs, including inpatient, outpatient, and pharmacy costs, were 29% lower for patients who received a medication for their opioid dependence, despite significantly higher costs for medications. Patients given XR-NTX had significantly fewer opioid-related and non–opioid-related hospitalizations than those given any of the 3 oral agents, fewer ED visits than patients who received methadone, and an overall pattern of the lowest use in all categories of inpatient utilization (Figure 2A). Despite significantly higher costs for XR-NTX, total healthcare costs, including inpatient, outpatient, and pharmacy costs, were not significantly greater than total costs with oral NTX or buprenorphine, and were 49% lower than with methadone (Figure 2D).

This retrospective claims analysis lacked clinical variables such as drug use, severity, and overdose; however, the rate of hospital admissions is an intensive utilization variable that may also represent a proxy for morbidity, which has importance in addition to cost implications. In this study, medication was associated with 29% lower costs than nonpharmacologic treatment, whereas the relative risk reduction associated with medication was 84% for opioid-related hospitalization and 60% for non–opioid-related admission. Of the 4 FDA-approved medications, the total cost associated with XR-NTX was not significantly different from oral NTX and buprenorphine, and it was 49% lower than that with methadone. However, Figure 2A shows that the risk of an opioid-related hospitalization in patients given XR-NTX was 36% lower than that with oral NTX, 63% less than with buprenorphine, and 53% less than with methadone; the risk for non–opioid-related hospitalization with XR-NTX was 40%, 41%, and 58% lower than that with oral NTX, buprenorphine, and methadone, respectively. Similar results have been reported in the treatment of alcohol dependence, with 3 large retrospective claims analyses showing that medication-assisted treatment was associated with lower total healthcare costs than nonmedication treatment.[29-31] Also, XR-NTX treatment cohorts demonstrated utilization and/or cost benefits in relation to approved oral agents for alcohol dependence.

These overall healthcare cost results highlight the problem of healthcare budget segmentation. The any medication group had total medication costs that were several times greater than those with no anti-opioid medications; however, overall healthcare costs were 29% less in those receiving opioid-dependence medication. Likewise, the cost of XR-NTX itself was more than 10-fold that of methadone, but total healthcare costs associated with methadone were nearly double those of XR-NTX. While many other factors must be taken into account, these findings suggest that stand-alone budgeting based on pharmacy costs may be counterproduc-

tive in addiction treatment—the cost offsets of a "carve out" arrangement may not accrue to medical cost centers.

Refill persistence and outcomes showed an inverse relationship among once-monthly XR-NTX and daily oral NTX. Once XR-NTX is administered by a healthcare professional, the active ingredient, NTX, is present for a month and cannot be removed from the system. Daily oral NTX, however, was found to be ineffective due to poor treatment adherence.[32] In the present study, 21% of patients receiving XR-NTX possessed the injection at least 80% of the study days, a percentage which was 2.6 times that with oral NTX (8%). The XR-NTX group had significantly fewer opioid-related and non–opioid-related hospitalizations. Compared with patients given XR-NTX, those given methadone or buprenorphine had similar refill persistence, and a greater percentage of these patients possessed their medication for at least 80% of the duration. This may reflect patient satisfaction, treatment effectiveness, and/or the fact that both agents have agonist properties that maintain opioid physical dependence and result in symptoms of withdrawal upon cessation.

Limitations of retrospective claims analyses include the absence of randomized controls. Therefore, treatment assignment resulted in imbalances in important clinical variables. There were substantial differences between the cohorts at baseline, some of which may have been unobserved (eg, differential patient motivation or provider characteristics). Possible reasons for these differences include regional differences in access to methadone and buprenorphine, differential reimbursement, and provider and community attitudes toward opioid-maintenance therapy and patient self-selection (eg, orientation toward an opioid-free recovery). These differences were particularly salient because at the time of data collection, XR-NTX was not yet approved by the FDA for opioid-dependence treatment, resulting in a notably smaller cohort receiving this medication. Patients who were seeking XR-NTX and prescribers offering it were possibly quite different from patients and providers utilizing other agents. The statistical methods we used, while designed to adjust for observed and unobserved differences and bias, may have been imperfect in this respect, and thus the observed findings may reflect unadjusted confounding.

Another limitation was that group sizes varied considerably in this study and, in general, studies of the relationship between rare exposures to a risk factor require large sample sizes to obtain reasonable estimates. The sample size for the XR-NTX group in particular was smaller than the other groups, raising questions about generalizability and the interpretation of statistical tests. However, the overall sample size was large, and the findings of the highest cost incidents for the XR-NTX comparisons show relatively good internal consistency, supporting the validity of the findings for this XR-NTX sample. Further research, however, should be conducted with larger samples for confirmation, now that XR-NTX is FDA-approved for opioid dependence. The index date for the any medication group permitted inclusion of a period of psychosocial treatment prior to medication-assisted treatment (in contrast to the no medication group), possibly leading to underestimated costs for the treatment episode in the medication group. We excluded patients who transitioned from one medication to another. It is not known what percentage of patients given oral NTX were subject to mandated or monitored administration (ie, to retain a professional license), what percentage of patients given buprenorphine intended to undergo detoxification only, or what percentage of patients given methadone were treated in a licensed methadone maintenance clinic versus receiving methadone for the treatment of pain outside of an opioid treatment program. Claims data do not record duration of opioid dependence or assessments of ongoing illicit drug use. No information was available regarding recommended or adequate durations of treatment, and daily treatment adherence could not be inferred by prescription refills. Medications have adverse effects, some of which are noted in boxed warnings in the prescribing information, and adverse effects differ between the oral and injectable agents; adverse events data were not examined. The 6-month study period did not provide long-term outcome data, and the patient population had some distinct characteristics, including having commercial insurance for a full year.

The study had some relevant strengths, despite these limitations. To establish comparability between cohorts, propensity-score matching was used for the any versus no medication comparison, and instrumental variable analysis was added to the 4-way medication comparison to control for both observed and unobserved bias. Refill possession duration was relatively brief, but this duration was real, and treatment effects were therefore examined during and beyond the average medication treatment duration. A good degree of internal consistency was apparent in the patterns of higher utilization of intensive services for the comparisons of no medication versus any medication and the 3 oral agents versus XR-NTX. Patients in this study were commercially insured and XR-NTX had yet to receive FDA approval for the treatment of opioid dependence; nevertheless, from the perspective of commercial insurance, these results would be expected to have external validity, given the large sample sizes for the no medication and oral medication cohorts, which consisted of real-world patients treated by community providers in standard treatment settings. Opioid agonist treatment in the

United States has traditionally been government funded, but 33.1% to 61.6% of public programs now report commercial insurance funding[33] and increasing commercial coverage is part of the National Drug Control Strategy.[3]

The vast majority (98.5%) of 270,881 patients enrolled in US opioid treatment programs are receiving methadone.[33] In the United States, the annual cost for counseling plus methadone services is at least $4700, whereas the combined mean costs of methadone plus opioid-related physician and psychosocial services in this study over 6 months was much less, suggesting that these data may underestimate the difference between XR-NTX and methadone costs.[1,34] Furthermore, this study raises a question about the medical care of patients receiving methadone. These data show a low use of physician providers and a very high use of ED services in patients given methadone, raising a quality-of-care issue that is worthy of further exploration.

This study's cost evaluation was limited to direct healthcare expenditures, but a review of 11 studies found that the largest source of cost benefit associated with substance abuse treatment was reduction in criminal activity, followed by improved earning potential; the contribution from healthcare was third.[35] Future studies should include these cost areas.

Regulatory, licensing, and financing policies have separated treatment of opioid addiction from medical care, significantly limiting access to care and further stigmatizing both individuals with these addictions and pharmacotherapy itself. For many years, it has been easier for individuals to acquire drugs than to receive treatment for addiction. The integration of opioid-dependence treatment into mainstream medicine is a key component of the White House's national drug strategy, but the barriers are numerous—training deficits, organizational obstacles, negative attitudes toward addictions, and fears about additional costs.[3] While methadone is limited to specially licensed programs, the other agents can be delivered in any clinical setting (eg, office-based physician practices and community health centers). Based on pretreatment comorbidity and utilization, patients in this study who received medication tended to be sicker at baseline. This supports the need for physician involvement in the care of patients with addiction. With medical treatment, total costs and use of inpatient services of all types were lower, supporting the potential cost benefit of increased integration of addiction and primary care services. This has been previously demonstrated in patients with substance abuse–related medical conditions.[36]

The majority of patients with opioid-dependence disorder in the United States remain untreated. Yet, the literature on cost-benefit studies with opioid agonist maintenance therapy consistently finds that benefits exceed costs, even when not all benefits are accounted for in the analysis.[37,38] The National Institute on Drug Abuse guide states that no single treatment is appropriate for all patients, that treatment needs to be readily available, and that medications are an important treatment element, in combination with behavioral approaches.[1] Further research is needed, with larger XR-NTX populations, for longer durations, and preferably with prospective designs or cohort-matching methods analogous to what were utilized in the present study. The current findings regarding opioid-dependence pharmacotherapy are compelling, and the cost findings regarding XR-NTX deserve further exploration in larger cohorts and trials using experimental designs that collect treatment outcome and cost data.

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***Author disclosures:*** Dr Gastfriend is an employee of Alkermes, Inc and reports owning stock in the company. Dr Fiellin reports honoraria from Pinney Associates. Dr Baser and Dr Chalk report no relationship or financial interest with any entity that would pose a conflict of interest with the subject matter of this article.

***Authorship information:*** Concept and design (MC, DRG); acquisition of data (OB); analysis and interpretation of data (OB, MC, DAF, DRG); drafting of the manuscript (OB, MC, DAF, DRG); critical revision of the manuscript for important intellectual content (MC, DAF, DRG); statistical analysis (OB); obtaining funding (DRG); and administrative, technical, or logistic support (DRG).

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# Public Policy Directory

This document provides contact information for organizational leaders who, to our knowledge, are utilizing VIVITROL® (naltrexone for extended-release injectable suspension). This is not intended to provide any claims of product safety or efficacy. All programs and individuals noted below are fully independent of Alkermes financial or in-kind support, unless otherwise noted. Some initiatives are listed in more than one section of this Directory.

Treatment with VIVITROL should be part of a comprehensive management program that includes psychosocial support. Opioid-dependent patients, including those being treated for alcohol dependence, must be opioid-free at the time of initial VIVITROL administration. VIVITROL is indicated for the treatment of alcohol dependence in patients who are able to abstain from alcohol in an outpatient setting prior to initiation of treatment with VIVITROL. Patients should not be actively drinking at the time of initial VIVITROL administration. VIVITROL is also indicated for the prevention of relapse to opioid dependence, following opioid detoxification.

## State Initiatives

| Name | Affiliation | Position | State | Email | Phone | Descriptions |
|---|---|---|---|---|---|---|
| Bonnie Campbell, LCSW | Baltimore Substance Abuse Systems | Director of Policy and Planning | MD | bcampbell@bsasinc.org | (410) 637-1900 Ext. 252 | VIVITROL initiated at both inpatient and outpatient locations for Alcohol Dependence. |
| Lucy Garrighan Short | JADE Wellness Center | CEO | PA | lucy@myjadewellness.com | (412) 400-5555 | Pennsylvania State Medicaid pilot for opioid dependence. The behavioral health plan is partnering with the managed medicaid plans. |
| Mark Stringer, M.A. | Missouri Department of Mental Health, Division of Alcohol and Drug Abuse | Director | MO | Mark.Stringer@dmh.mo.gov | (573) 751-4942 | Statewide implementation of VIVITROL paid for by the state for those under probation and parole supervision and for the uninsured. Program initiated in 2008. |
| Ximena Johnson | Florida Department of Children and Families, Substance Abuse Program Office | Performance Improvement Coordinator | FL | ximena_johnson@dcf.state.fl.us | (850) 717-4437 | VIVITROL offered in multiple centers in FL for high-risk, uninsured high-need patients. Expanded to criminal justice and veterans populations with recently-awarded ATR grant. Program initiated in |
| Stephanie Wick, MS | Department of Social and Rehabilitation Services, Addiction and Prevention | Director | KS | stephanie.wick@srs.ks.gov | (785) 296-6807 | High risk/high need patients through a collaboration between Kansas SSA and Value Options, and Regional Assessment Center. |
| Suzanne Borys | NJ Division of Mental Health and Addiction Services | Asst. Director, Research, Planning & Policy | NJ | Suzanne.borys@dhs.state.NJ.us | (609) 984-4050 | VIVITROL for DUI offenders including those with opioid dependence. |
| Wendy McCullough | Stairways Forensics Clinic | Director | PA | wmccullough@stairwaysbh.org | (814) 878-3472 | Pennsylvania State Medicaid pilot for opioid dependence. The behavioral health plan is partnering with the managed medicaid plans. |

## City & County-based Initiatives

| Name | Affiliation | Position | State | Email | Phone | Descriptions |
|---|---|---|---|---|---|---|
| Angela Johnsen, MSW | Warren County, OH, Mental Health Recovery Centers | Outpatient Director | OH | ajohnsen@mhrswcc.org | (513) 228-7877 | VIVITROL provided to reentering offenders leaving the county detention center, with the first injection planned prior to release. Continuing care with VIVITROL to occur in the community. |
| Beth Jones, MS,LCAC | Harford County Department, Division of Addiction Services | Director | MD | bethjones@dhmh.state.md.us | (410 )877-2360 | VIVITROL for high risk/high need patients. |
| Bonnie Campbell, LCSW | Baltimore Substance Abuse Systems | Director of Policy and Planning | MD | bcampbell@bsasinc.org | (410) 637-1900 Ext. 252 | VIVITROL initiated at both inpatient and outpatient locations for Alcohol Dependence. |
| Catherine McAlpine | Montgomery County | Director | MD | Catherine.McAlpine@montgomerycountymd.gov | (240) 777-4710 | VIVITROL provided for high-risk/high need patients, including drug courts participants. |
| Dr. Debra O'Beirne | Fairfax County, VA Engagement Program | Addiction Medicine Psychiatrist | VA | debra.O'Beirne@fairfaxcounty.gov | (703) 517-3620 | Vivitrol used as a tool to support recovery process in high-risk patients. |
| Holly McCravey | Los Angeles County Department of Public Health, Substance Abuse Prevention | Acting Program Administrator for Adult Treatment and | CA | hmccravey@ph.lacounty.gov | (626) 299-4197 | VIVITROL and case management for repeat detox population. Also, Vivitrol in 12 drug courts and planning jail re-entry initiatives. |
| Jana Kyle | Fayette County Drug and Alcohol Bureau | Director | PA | jkyle@fcdac.org | (724) 438-3576 | VIVITROL for high risk/high need patients. |
| Judi Rosser | Blair County Drug and Alcohol Bureau | Director | PA | jrosser@blairdap.org | (814) 693-9663 | VIVITROL for offenders in Drug Court. |
| Linda Gallagher | Hamilton County Mental Health and Recovery Services Board | Vice President AOD Services | OH | lindag@hamilton.mhrsb.state.oh.us | (513) 946-8690 | Vivitrol provided to opioid dependent drug court participants. Funded by SAMHSA drug court expansion grant. |
| Lisa Roberts, RN | Portsmouth Public Health Department | Public Health Nurse | OH | Lisa.Roberts@odh.ohio.gov | (740) 353-2418 Ext. 293 | VIVITROL provided to uninsured alcohol and opioid dependent patients. |
| Randy Spangle | Ashland County, Division of Mental Health and Substance Abuse Services | Director | WI | aac@ncis.net | (715) 682-5207 | VIVITROL provided for repeat DWI offenders. |
| Rebecca Hogamier, MBA, LCADC | Washington County, Division of Addiction and Mental Health Services | Director | MD | rhogamier@dhmh.state.md.us | (240) 313-3283 | VIVITROL provided to reentering offenders leaving the county detention center, with the first injection planned prior to release. Continuing care with VIVITROL to occur in the community. Note: This |
| Richard Wynn | Franklin/Fulton Drug and Alcohol Bureau | Human Services Director | PA | rcwynn@franklincountypa.gov | (717) 263-1256 | VIVITROL for high risk/high need patients. |
| Sue Doyle, RN | Carroll County | Director | MD | sdoyle@dhmh.state.md.us | (410) 876-4410 | VIVITROL provided for high-risk/high need patients in both residential and outpatient settings and also for Drug Court clients. |
| Sue Gadacz, MA | Milwaukee County Behavioral Health | Director | WI | Susan.Gadacz@milwcnty.com | (414)257-7023 | VIVITROL for clients in Milwaukee County Drug Courts; add'l initiative with repeat detox pts. |
| Tamara C. Feest | Oneida County OWI Court | OWI Court Administrator | WI | TF@thehumanservicecenter.org | (715) 369-2215 | VIVITROL for 3rd time OWI offenders. |

## Criminal Justice Settings

| Name | Affiliation | Position | State | Email | Phone | Descriptions |
|---|---|---|---|---|---|---|
| Carol Carlson | Milwaukee Drug Court | Court Coordinator | WI | ccarlson@JusticePoint.org | (414) 223-1341 | Vivitrol for Drug Court Offenders. |
| Christine Costa | Barnstable Community Corrections Center | Program Manager | MA | cti24@[redacted] | (774) 470-1375 | VIVITROL and treatment provided to probationers/parolees as part of the Office of Community Corrections treatment plan. |
| Gregg Dockins | Gateway Foundation | Director, Corrections Initiatives | MO | gdockins@gatewayfoundation.org | (815) 220-9058 | Vivitrol for probation and parole clients. |
| H. Bruce Hayden, LMHC, CAP | Banyan Health Systems | President & CEO | FL | bhayden@spectrumprograms.org | (305) 757-0602 | Program provides treatment with VIVITROL through the Florida Indigent Drug Program. |
| Hartwell Dowling, LCSW | Maine Administrative Office of the Courts | Specialty Court Manager and Grant Coordinator | ME | Hartwell.Dowling@courts.maine.gov. | (207) 287-4021 | Part of NEADCP Project. VIVITROL for opioid or alcohol drug court participants. |
| Holly McCravey | Los Angeles County Department of Public Health, Substance Abuse Prevention | Acting Program Administrator for Adult Treatment and | CA | hmccravey@ph.lacounty.gov | (626) 299-4197 | VIVITROL and case management for repeat detox population. Also, Vivitrol in 12 drug courts and planning a jail re-entry initiative. |
| Hon. Alan Blankenship | Stone County Drug Court | Judge | MO | alan.blankenship@courts.mo.gov | (417) 357-3085 | VIVITROL for Drug Court Offenders. |
| Hon. Carl Ashley | Milwaukee Drug Court | Judge | WI | carl.ashley@wicourts.gov | (414) 278-5316 | VIVITROL for Drug Court Offenders. |
| Hon. Dawnn Gruenburg | Warren Felony Drug Court | Judge | MI | dgruenburg@cityofwarren.org | (585) 574-4974 | VIVITROL for Drug Court Offenders; Judge Gruenburg's court participated in an evaluation of VIVITROL in Drug Courts. |
| Hon. Fred Moses | Hocking County Municipal Court | Judge | OH | fmoses@co.hocking.oh.us | (614) 404-8040 | Vivitrol provided to opioid dependent drug court participants. |
| Hon. Glen Yamahiro | Milwaukee Drug Court | Judge | Wi | glen.yamahiro@wicourts.gov | (414) 278-5316 | Vivitrol for Drug Court Offenders. |
| Hon. Harry L. Powazeck | California State Court, Superior Courts, San Diego County | Judge | CA | Call Judge Powazek | (760) 201-8113 | Vivitrol for drug court offenders. |
| Hon. Harvey Hoffman | Eaton County DWI Court | Judge | MI | HHoffman@eatoncounty.org | (517) 543-7500 Ext. 4030 | VIVITROL for DWI Court Offenders; Judge Hoffman's court participated in an evaluation of VIVITROL in Drug Courts. |
| Hon. James Kandrevas | Southgate Drug Court | Judge | MI | kgray@28dc.com | (734) 258-3068 | VIVITROL for Drug Court Offenders; Judge Kandrevas' court participated in an evaluation of VIVITROL in Drug Courts. |
| Hon. James Sullivan | St Louis Drug Court | Commissioner and Judge | MO | james.sullivan@courts.mo.gov | (314) 641-8212 | VIVITROL for Drug Court Offenders; Judge Sullivan's court participated in an evaluation of VIVITROL in Drug Courts. |
| Hon. John Marksen | Dane County OWI Court | Judge | WI | john.markson@wicourts.gov | (608) 266-4231 | VIVITROL for 3rd time OWI offenders. |
| Hon. Michael Noble | St Louis Drug Court | Commissioner/Judge | MO | mnoble1@courts.mo.gov | (314) 552-2030 | VIVITROL for DWI Court Offenders; Judge Noble's court participated in an evaluation of VIVITROL in Drug Courts. |
| Hon. Oscar Hale | Webb County Drug Court | Judge | TX | 406@webbcountytx.gov | (956) 523-5954 | Vivitrol for Drug Court Offenders. |
| Hon. Peggy Davis | Green County DWI Court | Commissioner and Judge | MO | Peggy.davis@courts.mo.gov | (417) 829-6620 | VIVITROL for DWI Court Offenders; Judge Davis' court participated in an evaluation of VIVITROL in Drug Courts. |
| Hon. Phil Britt | Stoddard County Drug Court | Judge | MO | phillip.britt@courts.mo.gov | (573) 888-7091 | VIVITROL for DWI Offenders. |
| Hon. Phillip Ohlms | St Charles DWI Court | Commissioner and Judge | MO | Phil.Ohlms@Courts.Mo.gov | (636) 949-7462 | VIVITROL for DWI Court Offenders. |

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|---|---|---|---|---|---|---|
| James Gibbs | Southgate Drug Court | Chief Probation Officer | MI | jgibbs@28thdistrictcourt.com | (734) 258-3068 Ext. 3643 | VIVITROL for Drug Court Offenders; Mr. Gibbs' court participated in an evaluation of VIVITROL in Drug Courts. |
| Jesse Hernandez | Webb County Drug Court | Director of Treatment | TX | lafamilia@[redacted] | (956) 795-0948 | Vivitrol for Drug Court Offenders. |
| John Hamilton, LMFT | Recovery Network of Programs, Inc. | CEO | CT | John.Hamilton@rnpinc.org | (203) 929-1954 | New England Regional Drug Court (NEADCP) project involving VIVITROL for drug court participants. Medication funded through State Medicaid. |
| Linda Gallagher | Hamilton County Mental Health and Recovery Services Board | Vice President AOD Services | OH | lindag@hamilton.mhrsb.state.oh.us | (513) 946-8690 | Vivitrol provided to opioid dependent drug court participants. Funded by SAMHSA drug court expansion grant. |
| Lt. Kristen Shea | Hampshire Sheriff's Department | Project Leader | MA | Kristen.shea@hsd.state.ma.us | (413) 584-5911 Ext:254 | VIVITROL and treatment provided to reentering offenders prior to leaving the county correctional facility and to continue into the community. |
| Mark Stanford, Ph.D. | Addiction Medicine and Therapy Division, Dept. of Alcohol and Drug Services, Santa Clara Co. | Director, Medication Assisted Treatment | CA | mark.stanford@hhs.sccgov.org | (408) 885-4078 | Vivitrol initiated in jail and continued in the community alcohol and drug programs. |
| Marta Nolan, PhD. | Missouri Department of Corrections | Asst Director, Substance Abuse Services | MO | Marta.Nolin@doc.mo.gov | (573) 522-1517 | DOC Pre-Release Pilot. |
| Marylin Gibson | Green County DWI Court | Drug Court Coordinator | MO | marilyn.gibson@courts.mo.gov | (417) 829-6620 | VIVITROL for Drug DWI Offenders; Ms. Gibson's court participated in an evaluation of VIVITROL in Drug Courts. |
| Michael Darcy | Gateway Foundation | CEO | IL | michael.darcy@gatewayfoundation.org | (312) 913-2316 | Vivitrol for probation and parole clients. |
| Mickey Williams, J.D. | St Louis Drug Court | Drug Court Administrator | MO | Keithley.Williams@courts.mo.gov | (314) 589-6702 | Court participated in Drug Court Evaluation. |
| Mickey Williams, J.D. | St Louis Drug Court | Drug Court Administrator | MO | MWillia4@courts.mo.gov | (314) 589-6702 | VIVITROL for Drug Court Offenders; Ms. Williams' court participated in an evaluation of VIVITROL in Drug Courts. |
| Patrick McCarthy, MS, LCSW, MBA | Hampden County Sheriff's Department | Director of Health Services | MA | pat.mccarthy@sdh.state.ma.us | (413) 858-0344 | VIVITROL and treatment provided to reentering offenders prior to leaving the county correctional facility and to continue into the community. |
| Randall Ambrosius | Wood County | Manager, Mental Health and AODA | WI | rambrosius@co.wood.wi.us | (715) 421-8849 | VIVITROL provided for repeat DWI offenders. |
| Randy Spangle | Ashland County | Director, Ashland County Council on AODA | WI | aac@ncis.net | (715) 682-5207 | VIVITROL provided for repeat DWI offenders . |
| Rebecca Hogamier, MBA, LCADC | Washington County, Division of Addiction and Mental Health Services | Director | MD | rhogamier@dhmh.state.md.us | (240) 313-3283 | VIVITROL provided to reentering offenders leaving the county detention center, with the first injection planned prior to release. Continuing care with VIVITROL to occur in the community. Initiative won SAMHSA Science to Service Award, 2013. |
| Rhonda Panda, BS, CAC, CCDP | Recovery Network of Programs | Drug Court Coordinator | CT | Rhonda.Panda@rnpinc.org | (203) 610-6410 Ext. 115 | Part of NEADCP Project. VIVITROL for opioid or alcohol drug court participants. |
| Rob Watson | Stone County Drug/DWI Court | Probation Officer | MO | Rob.Watson@doc.mo.gov | (417) 357-1216 | Vivitrol for Drug and DWI court clients. |
| Robin Edwards | St. Louis Drug Court | Drug Court Coordinator | MO | Robin.Edwards@courts.mo.gov | (314) 616-5102 | Vivitrol for Re-Entry initiative and newly created MAT docket. |
| Sheriff James M. Cummings | Barnstable County Sheriff's Office | Sheriff | MA | jcummings@bsheriff.net Note: Contact Jessica Burgess, MSN, RN, Asst Director Health Services, jBurgess@bsheriff.net | (508) 563-4302 | VIVITROL and treatment provided to reentering offenders prior to leaving the county correctional facility and to continue in the community post release. |
| Sheriff Peter J. Koutoujian | Middlesex County Sheriff's Office | Sheriff | MA | Note: Contact Superintendent Sean McAdam at smcadam@sdm.state.ma.us | (978) 932-3376 | VIVITROL and treatment provided to reentering offenders prior to leaving the county correctional facility and to continue in the community post release. |
| Tim Griffin | Colorado Department of Corrections | Special Project Manager | CO | tgcolorado@[redacted] | (303) 704-2410 | Vivitrol Pilot for Parole Violators. |
| Wendy McCullough | Stairways Forensics Clinic | Director | PA | wmccullough@stairwaysbh.org | (814) 878-3472 | Providing Vivitrol for alcohol and opioid dependent parole and probation clients. |

## Public Health Center - Federally Eligible 340B Settings

| Name | Affiliation | Position | State | Email | Phone | Descriptions |
|---|---|---|---|---|---|---|
| Brenda Boetel | Pennington County Sheriff's Department, City/County Alcohol and Drug Programs | Director | SD | brendab@co.pennington.sd.us | (605) 394-6128 Ext. 204 | VIVITROL for high-risk/high need patients; Medication provided at Federally Qualified Health Center (FQHC). |
| David Swann, M.A. | Crossroads Behavioral Healthcare | CEO | NC | DSwann@crossroadsbhc.org | (336) 835-1001 Ext. 1104 | VIVITROL integrated into Federally Qualified Health Center (FQHC). |
| Dorsey Ward, MSW | Carolina Medical Center | Executive Director | NC | ward@carolinashealthcare.org | (704) 283-2043 | VIVITROL provided at a Federally Qualified Health Center (FQHC). |
| Jeff Berman, MD | Bergen Regional Medical Center | Medical Director | NJ | JBerman@bergenregional.com | (201) 394-7491 | Integrated VIVITROL into a Disproportionate Share Hospital's (DSH) inpatient specialty service and large primary care services. |
| Jone Payton, RN | Portsmouth Public Health Department | Rural AIDS/Community Grants Coordinator | OH | Jone.Payton@odh.ohio.gov | (740) 353-5153 Ext. 234 | VIVITROL provided to uninsured alcohol and opioid dependent patients. |
| Mark Stanford, Ph.D. | Santa Clara County, Addiction Medicine & Therapy Division | Director | CA | Mark.Stanford@hhs.scc.gov | (408) 885-4078 | VIVITROL initiated in county jail and then subsequent doses administered in FQHC; program evaluation planned. |

## Tribal Settings

| Name | Affiliation | Position | State | Email | Phone | Descriptions |
|---|---|---|---|---|---|---|
| Ann Bruce MD | Suquamish Tribe | Medical Director | WA | abruce@suquamish.nsn.us | (360) 394-8558 | A Vivitrol program within the Suquamish Tribe, Suquamish WA, First dose delivered either in hospital post detox or in jail. |
| Dan Cable CDP | Muckleshoot Tribe | Supervisor Addictions Program | WA | dan.cable@muckleshoot-health.com | (253) 939-6648 | A Vivitrol program within the Muckleshoot tribe, Auburn WA. First dose delivered either in hospital post detox or jail. |
| Hon. Bradley Dakota | Keweenaw Bay Indian Community | KBIC Tribal Court | MI | tcbrad@up.net | (906) 353-8124 | Vivitrol being provided for tribal court clients. |
| Ted Hall, PharmD | Ho-Chunk Nation | Chief Pharmacist | WI | Ted.Hall@ho-chunk.com | (608) 355-1240 Ext. 5582 | A VIVITROL program within the Ho-Chunk Nation in Wisconsin. |

## Veterans Administration Healthcare Settings

| Name | Affiliation | Position | State | Email | Phone | Descriptions |
|---|---|---|---|---|---|---|
| Bernard J. Plansky, MD | Loyola Recovery Foundation, Inc. | Medical Director | NY | bplansky@loyolarecovery.com | (585) 203-1264 | Outpatient intervention to High Risk/High Need veterans utilizing VIVITROL coordinated with VA Patient Centered Medical Homes. |
| Donald "Hugh" Myrick, MD | Medical University of South Carolina; Ralph H. Johnson VA | Associate Chief of Staff | SC | myrickh@musc.edu | (843) 792-5212 | Utilizing VIVITROL with veterans. |
| Leonardo Rodriguez, MD | Malcom Randall VA Medical Center, Gainesville FL | Clinical Expert | FL | Leonardo.Rodriguez@va.gov | (352) 376-1611 Ext. 6875 | Utilizing VIVITROL with veterans. |
| Thomas Kosten, MD | Baylor College of Medicine; Michael E. DeBakey VA Medical | Director, Division of Alcohol & Addiction Psychiatry | TX | kosten@bcm.tmc.edu | (713) 794-7032 | Utilizing VIVITROL with veterans. |

## Community Mental Heath Centers

| Name | Affiliation | Position | State | Email | Phone | Descriptions |
|---|---|---|---|---|---|---|
| Amanda Albertsen, MD | Peninsula Outpatient Clinic | Nurse Practitioner | TN | abelkins@[redacted] | (865) 970-9800 | Community mental health centers using Vivitrol with alcohol and opioid dependence. |
| Bruce Hayden, LMHC, CAP | Banyan Health Systems | CEO | FL | bhayden@spectrumprograms.org | (305) 398-6128 | Community mental health centers using Vivitrol with alcohol and opioid dependence. |
| Dean Babcock, MSW | Wishard Health Services | Associate Vice President | IN | Dean.Babcock@wishard.edu | (317) 630-7791 | Using Vivitrol in a community mental health centers in the treatment of individuals with AD, OD and co-occurring mental health problems. |
| Dora Davis, RN | Logan/Mingo Area Mental Health | Public Health Nurse | WV | | (304) 792-7130 | Community mental health centers using Vivitrol with alcohol and opioid dependence. |
| Karen Brewer, RN | Wood County Dept. of Human Services | Public **Health** Nurse | WI | kbrewer@co.wood.wi.us | (715) 421-8863 | Community mental health centers using Vivitrol with alcohol and opioid dependence. |
| Paula Brawner | Preferred Family Behavioral Health | CEO | MO | pbrawner@pfh.org | (660) 665-1962 | Using Vivitrol in a community mental health centers in the treatment of individuals with AD, OD and co-occurring mental health problems. |

## Therapeutic Communities

| Name | Affiliation | Position | State | Email | Phone | Descriptions |
|---|---|---|---|---|---|---|
| Ken Bachach, PhD | Tarzana | VP, Clinical | CA | kbachrach@tarzanatc.org | (818) 654-3806 | Large multi-site treatment system, using Vivitrol for AD and OPD. |
| Michael Darcy | Gateway Foundation | CEO | IL | michael.darcy@gatewayfoundation.org | (312) 913-2316 | Vivitrol for clients with AD and OPD. |
| Steven Margolies, MD | Phoenix House | Medical Director, NY State Region | NY | slmargolies@phoenixhouse.org | (718) 726-8484 Ext. 3790 | Large multi-site treatment system, using Vivitrol for AD and OPD; justice system involvement. |

## Rural Settings

| Name | Affiliation | Position | State | Email | Phone | Descriptions |
|---|---|---|---|---|---|---|
| Bernard J. Plansky, MD | Loyola Recovery Foundation, Inc. | Medical Director | NY | bplansky@loyolarecovery.com | (585) 203-1264 | Outpatient intervention to High Risk/High Need veterans utilizing VIVITROL coordinated with VA Patient Centered Medical Homes. |
| Ted Hall, PharmD | Ho-Chunk Nation | Chief Pharmacist | WI | Ted.Hall@ho-chunk.com | (608) 355-1240 Ext. 5582 | A VIVITROL program within the Ho-Chunk Nation in Wisconsin. |

## Public Policy-Related Research*

| Name | Affiliation | Position | State | Email | Phone | Descriptions |
|---|---|---|---|---|---|---|
| Charles P. O'Brien, MD, PhD | University of Pennsylvania School of Medicine, Center for Addiction Studies | Director & Vice-Chair Psychiatry | PA | obrien@mail.trc.upenn.edu | (215) 222-3200 Ext.132 | Lead investigator of NIDA-sponsored, multi-site study assessing efficacy of VIVITROL with opioid dependent probationers and parolees. |
| Edward Nunes, MD | Columbia University | Professor of Clinical Psychiatry | NY | nunesed@pi.cpmc.columbia.edu | (212) 543-5581 | Investigator for the NIDA-sponsored, multi-site study assessing efficacy of VIVITROL with opioid dependent probationers and parolees. |
| Frederick Altice, MD | Yale University | Professor of Medicine | CT | frederick.altice@yale.edu | (203) 737-2883 | Co-lead investigator for a NIAAA-sponsored study of VIVITROL for reentering inmates who are HIV+ and have an alcohol problem. |
| Joshua Lee, MD | New York University | Professor of Medicine | NY | joshua.lee@nyumc.org | (212) 263-4242 | Lead investigator for a pilot study of VIVITROL for opioid dependent inmates prior to release from Rikers Island. |
| Marc Gourevitch MD, MPH | New York University | Director, Internal Medicine | NY | marc.gourevitch@med.nyu.edu | (212) 263-8553 | Published on integration of VIVITROL into a primary care practices at Gouverneur and Bellevue Hospitals (NYU). |
| Sandra Springer, MD | Yale University | Assistant Professor of Medicine | CT | sandra.springer@yale.edu | (203) 737-5530 | Lead investigator for a NIAAA-sponsored study of VIVITROL for reentering inmates who are HIV+ and have an alcohol problem. |
| Susan E. Collins, PhD | University of Washington-Harborview Medical Center | Director | WA | collinss@uw.edu | (206) 832-7885 | Conducting study of Vivitrol for homeless alcoholics. |

*Alkermes provided VIVITROL free of charge for use in these studies pursuant to the Alkermes' Investigator Initiated Trial application process.

## Alkermes Public Policy Team Member Contacts

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| Robert Forman, PhD | Director, Professional Relations | Federal Public Policy | | Robert.Forman@alkermes.com | (617) 899-2646 | |
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## IMPORTANT SAFETY INFORMATION FOR VIVITROL® (naltrexone for extended-release injectable suspension)

**INDICATIONS**
VIVITROL is indicated for:
• Treatment of alcohol dependence in patients who are able to abstain from alcohol in an outpatient setting. Patients should not be actively drinking at the time of initial VIVITROL administration.
• Prevention of relapse to opioid dependence, following opioid detoxification.
• VIVITROL should be part of a comprehensive management program that includes psychosocial support.

**CONTRAINDICATIONS**
VIVITROL is contraindicated in patients:
• Receiving opioid analgesics
• With current physiologic opioid dependence
• In acute opioid withdrawal
• Who have failed the naloxone challenge test or have a positive urine screen for opioids
• Who have exhibited hypersensitivity to naltrexone, polylactide-co-glycolide (PLG), carboxymethylcellulose, or any other components of the diluent

**WARNINGS/PRECAUTIONS**
Vulnerability to Opioid Overdose: Because VIVITROL blocks the effects of exogenous opioids for approximately 28 days after administration, patients are likely to have a reduced tolerance to opioids after opioid detoxification. As the blockade dissipates, use of previously tolerated doses of opioids could result in potentially life-threatening opioid intoxication (respiratory compromise or arrest, circulatory collapse, etc). Cases of opioid overdose with fatal outcomes have been reported in patients who used opioids at the end of a dosing interval, after missing a scheduled dose, or after discontinuing treatment. Patients and caregivers should be told of this increased sensitivity to opioids and the risk of overdose.

Any attempt by a patient to overcome the VIVITROL blockade by taking opioids may lead to fatal overdose. Patients should be told of the serious consequences of trying to overcome the opioid blockade.

**Injection Site Reaction**s: VIVITROL injections may be followed by pain, tenderness, induration, swelling, erythema, bruising, or pruritus; however, in some cases injection site reactions may be very severe. Injection site reactions not improving may require prompt medical attention, including, in some cases, surgical intervention. Inadvertent subcutaneous/adipose layer injection of VIVITROL may increase the likelihood of severe injection site reactions. Select proper needle size for patient body habitus, and use only the needles provided in the carton. Patients should be informed that any concerning injection site reactions should be brought to the attention of their healthcare provider.

**Precipitation of Opioid Withdrawal:** Withdrawal precipitated by administration of VIVITROL may be severe. Some cases of withdrawal symptoms have been severe enough to require hospitalization and management in the ICU. To prevent precipitated withdrawal, patients, including those being treated for alcohol dependence:
• Should be opioid-free (including tramadol) for a minimum of 7–10 days before starting VIVITROL.
• Patients transitioning from buprenorphine or methadone may be vulnerable to precipitated withdrawal for as long as two weeks.

Patients should be made aware of the risk associated with precipitated withdrawal and be encouraged to give an accurate account of last opioid use.

**Hepatotoxicity:** Cases of hepatitis and clinically significant liver dysfunction have been observed in association with VIVITROL. Warn patients of the risk of hepatic injury; advise them to seek help if experiencing symptoms of acute hepatitis. Discontinue use of VIVITROL in patients who exhibit acute hepatitis symptoms.

**Depression and Suicidality:** Alcohol- and opioid-dependent patients taking VIVITROL should be monitored for depression or suicidal thoughts. Alert families and caregivers to monitor and report the emergence of symptoms of depression or suicidality.

**When Reversal of VIVITROL Blockade Is Required for Pain Management:** For VIVITROL patients in emergency situations, suggestions for pain management include regional analgesia or use of non-opioid analgesics. If opioid therapy is required to reverse the VIVITROL blockade, patients should be closely monitored by trained personnel in a setting staffed and equipped for CPR.

**Eosinophilic Pneumonia:** Cases of eosinophilic pneumonia requiring hospitalization have been reported. Warn patients of the risk of eosinophilic pneumonia and to seek medical attention if they develop symptoms of pneumonia.

**Hypersensitivity Reactions:** Patients should be warned of the risk of hypersensitivity reactions, including anaphylaxis.

**Intramuscular Injections:** As with any IM injection, VIVITROL should be administered with caution to patients with thrombocytopenia or any coagulation disorder.

**ADVERSE REACTIONS**
Serious adverse reactions that may be associated with VIVITROL therapy in clinical use include severe injection site reactions, eosinophilic pneumonia, serious allergic reactions, unintended precipitation of opioid withdrawal, accidental opioid overdose, and depression and suicidality. The adverse events seen most frequently in association with VIVITROL therapy for alcohol dependence include nausea, vomiting, injection site reactions (including induration, pruritus, nodules, and swelling), muscle cramps, dizziness or syncope, somnolence or sedation, anorexia, decreased appetite or other appetite disorders. The adverse events seen most frequently in association with VIVITROL in opioid-dependent patients also include hepatic enzyme abnormalities, injection site pain, nasopharyngitis, insomnia, and toothache.

**PLEASE SEE THE PRESCRIBING INFORMATION, AND MEDICATION GUIDE. PLEASE REVIEW THE MEDICATION GUIDE WITH YOUR PATIENTS.**

Substance Abuse and Mental Health Services Administration
SAMHSA ADVISORY
www.samhsa.gov • 1-877-SAMHSA-7 (1-877-726-4727)



# An Introduction to Extended-Release Injectable Naltrexone for the Treatment of People With Opioid Dependence

The U.S. Food and Drug Administration (FDA) approved extended-release injectable naltrexone (Vivitrol) in October 2010 to treat people with opioid dependence. This medication provides patients with opioid dependence the opportunity to take effective medication monthly, as opposed to the daily dosing required by other opioid dependence medications (i.e., methadone, buprenorphine, oral naltrexone). Extended-release injectable naltrexone was approved by FDA in 2006 to treat people with alcohol dependence.

Treatment of opioid dependence remains a national priority. According to the 2010 *National Survey on Drug Use and Health*, approximately 359,000 individuals reported either dependence on or abuse of heroin, and 1.92 million individuals reported either dependence on or abuse of prescribed painkillers.[1] *The Treatment Episode Data Set* (TEDS) reports that between 1998 and 2008 the percentage of individuals ages 12 and older who entered substance abuse treatment because of pain reliever abuse increased more than fourfold—from 2.2 percent to 9.8 percent.[2]

This *Advisory* provides behavioral health professionals—including substance abuse treatment specialists—and primary care medical providers (who treat people with opioid dependence) with an introduction to extended-release injectable naltrexone. It includes succinct information about extended-release injectable naltrexone, how it compares with other medication-assisted treatment (MAT) options, and clinical strategies that may be used to select, initiate, and administer treatment.

## What Role Can Extended-Release Injectable Naltrexone Play in the Treatment of Opioid Dependence?

Extended-release injectable naltrexone is another pharmacological tool that is approved for treatment of people with opioid dependence. Over the years, medications have been successful in treating many patients with opioid dependence. Methadone has been used to treat patients for decades and has been proven effective.[3] However, methadone must be dispensed to the patient at a Substance Abuse and Mental Health Services Administration (SAMHSA)-certified opioid treatment program (OTP) facility—with daily doses provided at the clinic—until the patient is deemed stable enough to receive take-home doses. Barriers to accessing this treatment include limited geographical locations of OTPs, transportation difficulties, and policies that preclude the use of methadone.

Buprenorphine, approved in 2002 by FDA to treat opioid dependence, is available at OTPs but is most often prescribed by physicians in office-based settings. Thus, in theory, it can be more accessible than methadone. However, to prescribe buprenorphine, physicians need limited special training and so all physicians may not currently be able to prescribe it. Physicians also need to be granted a waiver by the U.S. Drug Enforcement Agency (DEA) from regulations that otherwise prohibit them from treating people with opioid dependence in office settings and, at maximum, can only treat up to 100 patients at a time. Currently, mid-level practitioners (e.g., nurse practitioners, physician assistants) are not eligible for DEA waivers to prescribe buprenorphine.

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Naltrexone can be prescribed by any healthcare provider who is licensed to prescribe medications. Special training is not required; the medication can be administered in OTP clinics. Practitioners in community health centers or private office settings can also prescribe it for purchase at the pharmacy. These factors may improve access to treatment for opioid dependence.

Naltrexone requires that patients be abstinent from opioids for a period prior to induction. Such abstinence can be difficult for patients to achieve. Retention in treatment has sometimes been problematic when patients are asked to adhere to daily doses of oral naltrexone.[4] A monthly injection of naltrexone, instead of daily dosing, may improve patients' adherence to their medication regimens.[5,6]

Extended-release injectable naltrexone has a higher pharmacy cost than buprenorphine and methadone, but some data suggest that its use may reduce inpatient admissions, emergency room visits, and other health system costs.[7] Nonetheless, the higher pharmacy cost of extended-release injectable naltrexone may limit access for patients who lack health insurance or other financial resources.

## How Does Extended-Release Injectable Naltrexone Differ From Other Forms of MAT for Opioid Dependence?

Both methadone and buprenorphine are controlled substances, whereas naltrexone is not. Methadone is an opioid agonist, buprenorphine is a partial opioid agonist, and naltrexone is an opioid antagonist.

Different types of opioid receptors—or molecules to which opioid compounds attach themselves and exert their effects—are present in the brain. Agonists are drugs that activate these receptors, binding to them and producing an effect. Opioids such as methadone, morphine, and heroin are full agonists and have the greatest abuse potential. Antagonists also bind to opioid receptors, but rather than producing an effect, they block the effects of opioid compounds. Partial agonists bind to the receptors and activate them, but not to the same degree as full agonists.[8]

Naltrexone has no abuse potential, whereas methadone and buprenorphine do. Further information about the pharmacology of methadone can be found in Treatment Improvement Protocol (TIP) 43: *Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs*.[9] Additional information about buprenorphine is available in TIP 40: *Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction*.[8]

Some physicians are reluctant to prescribe agonists to treat opioid dependence because of their treatment philosophies, difficulties in tapering patients off these medications, or the potential for illicit diversion of agonist medications.[5] Physicians with these concerns may be more comfortable prescribing an antagonist, such as naltrexone, rather than agonists.

Exhibit 1 summarizes key differences between extended-release injectable naltrexone, buprenorphine, and methadone.

## How Does Extended-Release Injectable Naltrexone Work?

Naltrexone is an opioid antagonist, a medication that binds to and effectively blocks opioid receptors.[8,10] It prevents receptors from being activated by agonist compounds, such as heroin or prescribed opioids, and is reported to reduce opioid cravings and to prevent relapse.[11,12] Patients need to be informed that this medication will prevent them from feeling the euphoric effect or pain relief they previously felt when they took an opioid.[10,13,14]

## Are There Safety Concerns About Extended-Release Injectable Naltrexone?

### Risk of accidental opioid overdose and death

Accidental overdoses and overdose-related deaths have occurred among patients who have taken opioids while being treated for opioid dependence with naltrexone-containing products—including both the extended-release injectable formulation and the daily oral formulation.[15,16] Overdoses and overdose-related deaths are also a risk with

agonist therapies. No comprehensive mortality data are yet available about extended-release injectable naltrexone, but cases of fatal opioid overdose have been reported in patients who:

- Used opioids at or near the end of the 1-month dosing interval.
- Used opioids after missing a dose of extended-release injectable naltrexone.
- Attempted to overcome the opioid blockade.[10]

Patients who have been treated with extended-release injectable naltrexone may have reduced tolerance to opioids and may be unaware of their potential sensitivity to the same, or lower, doses of opioids that they used to take. If patients who are treated with extended-release injectable naltrexone relapse after a period of abstinence, it is possible that the dosage of opioid that was previously used may have life-threatening consequences, including respiratory arrest and circulatory collapse.[10]

Physicians have an obligation to educate patients who are treated with naltrexone-containing products about mortality risks that exist during and after leaving treatment for opioid dependence.[13,17] Behavioral health providers may play a role in reminding patients of these risks. It is recommended that providers and patients develop a relapse prevention plan that includes strategies to decrease the risks if relapse occurs. If patients continue to use opioids during treatment, transition to agonist medications may be considered to reduce mortality risk, although these medications also have mortality risks.[13,17]

## Risk of precipitating withdrawal

Naltrexone displaces heroin or prescribed opioids from receptors to which they have bound, which can precipitate withdrawal symptoms.[8,20] Therefore, complete detoxification from opioids before initiating or resuming extended-release injectable naltrexone is necessary to prevent withdrawal. At least 7–10 days without opioid use is recommended before beginning extended-release injectable naltrexone.[10,16]

### Exhibit 1: Key Differences Between Medications Used To Treat Patients With Opioid Dependence

| Prescribing Considerations | Extended-Release Injectable Naltrexone | Buprenorphine | Methadone |
|---|---|---|---|
| **Frequency of Administration** | Monthly | Daily | Daily |
| **Route of Administration** | Intramuscular injection in the gluteal muscle by healthcare professional. | Oral tablet or film is dissolved under the tongue. Can be taken at a physician's office or at home. | Oral (liquid) consumption usually witnessed at an OTP, until the patient receives take-home doses. |
| **Restrictions on Prescribing or Dispensing** | Any individual who is licensed to prescribe medicine (e.g., physician, physician assistant, nurse practitioner) may prescribe and order administration by qualified staff. | Only licensed physicians who are DEA registered and either work at an OTP or have obtained a waiver to prescribe buprenorphine may do so. | Only licensed physicians who are DEA registered and who work at an OTP can order methadone for dispensing at the OTP. |
| **Abuse and Diversion Potential** | No | Yes | Yes |
| **Additional Requirements** | None; any pharmacy can fill the prescription. | Physicians must complete limited special training to qualify for the DEA prescribing waiver. Any pharmacy can fill the prescription. | For opioid dependence treatment purposes, methadone can only be purchased by and dispensed at certified OTPs or hospitals. |

Sources: Adapted from [16,18,19]

## Adverse events

The most frequently reported adverse events include hepatic enzyme abnormalities, injection site pain, common cold symptoms, insomnia, and toothache. Nausea, vomiting, muscle cramps, dizziness, sedation, decreased appetite, and an allergic form of pneumonia have also occurred in people treated with extended-release injectable naltrexone.[10,21]

### Injection site reactions

Injection site reactions—including pain, hardness, swelling, blisters, redness, bruising, abscesses, and tissue death—have been reported to FDA. Some reactions are serious enough that surgery is needed.[16]

To reduce the risk of serious injection site reactions:

- Extended-release injectable naltrexone should be administered as an intramuscular injection into the gluteal muscle using the specially designed administration needle provided. It should never be administered intravenously, subcutaneously, or inadvertently into fatty tissues.
- Extended-release injectable naltrexone should be administered into alternating buttocks (sides of the patient) each month.
- Healthcare providers should consider alternate treatments for patients whose body size, shape, or posture makes it impossible to administer extended-release injectable naltrexone in the recommended location. Note that the needle provided is not a standard needle (see last bullet). It is not possible to substitute a standard needle of a longer length.
- Patients who develop injection site reactions that do not improve should be referred to a surgeon.
- The packaging of extended-release injectable naltrexone was changed in 2010. Both 1.5- and 2-inch needles are included for injecting the medication, to accommodate patients' different body sizes. Use the 2-inch needle for most patients and reserve the shorter needle for lean patients.[10,16]

### Liver adverse effects

The FDA requires warnings on formulations of naltrexone about possible liver adverse effects. The current product labeling for extended-release injectable naltrexone includes a warning about hepatotoxicity when the medication is given in more than the recommended dose. Use of the medication is contraindicated in patients with acute hepatitis or liver failure. The medication manufacturer states that the margin of separation between the apparently safe dose and the dose causing hepatic injury appears to be only fivefold or less.[10] Extended-release injectable naltrexone should be discontinued if signs or symptoms of hepatitis develop (e.g., fatigue, loss of appetite, nausea, vomiting, abdominal pain, gray-colored bowel movement, joint pain, jaundice).[10] Further research and postmarket surveillance are underway to determine any long-term effects of this formulation on the liver.

## Which Patients May Benefit Most From Treatment With Extended-Release Injectable Naltrexone?

It is difficult to predict which medication will work for a particular patient with opioid dependence. Factors affecting a patient's treatment success with a medication may change over time or with subsequent treatment attempts. Extended-release injectable naltrexone benefits people with opioid dependence who are at risk for opioid use immediately after detoxification.[6] People facing periods of greatly increased stress or other relapse risks (e.g., visiting places of previous drug use, loss of spouse, loss of job) may find they benefit from the reassurance of the blockade provided by the medication.[11,13] People who have a short or less severe history of dependence may also want to consider injectable naltrexone.[6] Still others may have to demonstrate to professional boards, supervisors, drug court judges, or other authorities that their risk of using a nonprescribed opioid is low and the extended-release formulation may provide an option that has reduced risk compared with other options. No definitive research is available that states which patients would most benefit from extended-release injectable naltrexone, but the following people may be good candidates for treatment.

### People who have not had treatment success with methadone or buprenorphine

Depending on the reasons for treatment failure, people with opioid dependence who have not been successful with treatment with methadone or buprenorphine may benefit from extended-release injectable naltrexone.[22]

### People who have a high level of motivation for abstinence

People who are highly motivated to achieve and maintain abstinence from opioids may be good candidates for extended-release injectable naltrexone.[12,23] This includes people who are required to demonstrate abstinence with drug screens, such as individuals in impaired healthcare provider programs, parolees, probationers, and airline pilots.[24] Preliminary results from an ongoing study of U.S. healthcare professionals with opioid dependence suggest that this treatment can be successful for up to 1 year.[25]

### People successful on agonists who wish to change their medication or patients not interested in agonist therapy to treat their opioid dependence

Some patients may be successful on agonist treatment and want continued pharmacologic help to prevent relapse but would prefer another type of treatment,[22] while other patients may never be interested in agonist therapy. These types of patients could include individuals who:

- Feel they are discriminated against, or are embarrassed or ashamed, because they are on methadone maintenance or who previously experienced these emotions while undergoing methadone therapy.[26]
- Would like to reduce the time devoted to daily or multiple OTP visits per week, as is often required for methadone treatment.[13]
- Prefer to receive office-based treatment in a primary medical care setting, rather than treatment in specialty clinics or treatment centers.[24,26]

### Adolescents or young adults with opioid dependence

Methadone or buprenorphine are not always available to treat young people with opioid dependence because of OTP facility policies or governmental regulations. However, the safety and efficacy of extended-release injectable naltrexone have not been established for patients who are younger than age 18, and use for this population is not approved by FDA. Only limited experience in treating this population with extended-release injectable naltrexone is reported in the literature.[26]

## Can Extended-Release Injectable Naltrexone Be Used With Behavioral Therapies?

For most patients with opioid dependence, medications alone are insufficient. Treatment in individual or group counseling sessions and participation in mutual-help programs are also needed. Patients have better treatment outcomes when naltrexone-based treatment is combined with behavioral therapies.[4,6,27] The efficacy of extended-release naltrexone has been established when given in conjunction with behavioral support; it has not been studied as a sole component of treatment.

Healthcare providers should be ready to offer brief intervention if patients relapse during treatment of opioid dependence. Motivational interviewing and relapse prevention strategies may also enhance the effectiveness of pharmacological treatments.[8]

## How Can Pain Be Treated During or After Extended-Release Injectable Naltrexone Treatment?

Pain management in people receiving all forms of MAT, including extended-release injectable naltrexone, can be challenging. Some people can be safely and effectively treated with nonpharmacologic remedies, such as physical therapy, massage, or acupuncture, as long as the injection site is protected. Pain relief may also be obtained from nonopioid topical medications, nonsteroidal anti-inflammatory agents, regional blocks,

and nonopioid painkillers such as gabapentin and atypical antidepressants.[13]

Use of opioid-containing analgesics may aggravate preexisting addiction disorders and cause relapse. People with opioid dependence who require opioid therapy for chronic pain should be managed by pain management specialists. In light of its antagonist property, extended-release injectable naltrexone may not be appropriate for these patients.[22]

## Reversing blockade of opioid receptors

There are few clinical trial data available about reversing the opioid receptor blockade. When surgeries or procedures are planned for patients who use extended-release injectable naltrexone, it may be safest to delay the procedure until naltrexone blood levels are low enough to restore opioid receptor availability. The manufacturer of extended-release injectable naltrexone also suggests considering use of regional analgesia or nonopioid analgesics.[10]

In emergencies, it is possible for healthcare providers to reverse extended-release injectable naltrexone's opioid receptor blockade. However, higher than usual dosages of a rapidly acting opioid medication may be needed to achieve pain relief if a patient still has a tolerance to opioids. These higher dosages increase the risk of respiratory depression. Patients administered such high doses should be closely monitored by professionals trained in the use of anesthetic drugs, management of respiratory depression, and the performance of cardiopulmonary resuscitation.[10,16]

Patients who are treated with extended-release injectable naltrexone should be encouraged to wear medical alert jewelry or carry a disclosure card to help emergency personnel provide pain management safely when these patients are unconscious or cannot otherwise communicate.

# Resources

Several publications are available free of charge from SAMHSA. The resources listed below can be ordered from SAMHSA's Publications Ordering Web page at http://www.store.samhsa.gov. Or call 1-877-SAMHSA-7 (1-877-726-4727) (English and Español). Publications can also be downloaded from the Knowledge Application Program Web site at http://www.kap.samhsa.gov.

## Resources for professionals

*Substance Abuse Treatment Advisory: Naltrexone for Extended-Release Injectable Suspension for Treatment of Alcohol Dependence*. (2007). Volume 6, Issue 1. HHS Publication No. (SMA) 07-4267.

*Substance Abuse Treatment Advisory: Emerging Issues in the Use of Methadone*. (2009). Volume 8, Issue 1. HHS Publication No. (SMA) 09-4368.

Treatment Improvement Protocol (TIP) 40: *Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction*. (2004). HHS Publication No. (SMA) 07-3939.

TIP 43: *Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs*. (2005). HHS Publication No. (SMA) 08-4214.

TIP 45: *Detoxification and Substance Abuse Treatment*. (2006). HHS Publication No. (SMA) 08-4131.

## Resources for clients

*The Facts About Naltrexone for Treatment of Opioid Addiction*. (2009). HHS Publication No. (SMA) 09-4444.

*Medication-Assisted Treatment for Opioid Addiction: Facts for Families and Friends.* (2009). HHS Publication No. (SMA) 09-4443.

## Other Web resources for medical and health professionals

**National Institute on Drug Abuse, NIDAMED**
http://www.drugabuse.gov/nidamed

**U.S. Food and Drug Administration**
http://www.fda.gov

For specific information on extended-release injectable naltrexone: http://www.accessdata.fda.gov/drugsatfda_docs/label/2010/021897s005s010lbl.pdf

For specific information on adverse injection site reactions: http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm103334.htm

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## *SAMHSA Advisory*

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**Scott.A.Milkey**

**From:** Karns, Allison
**Sent:** Thursday, October 02, 2014 3:42 PM
**To:** Hill, John (DHS)
**Subject:** FW: Introduction
**Attachments:** AlcoholOutcomes,andPharmacotherapyPersistenceBaser_AJMC-2011.pdf.pdf; OutcomesofOpioid-DependenceTreatmentsBaser_AJMC-2011.pdf.pdf; PolicyDirectoryforCCCSubmission8-26-13.pdf; SAMHSA ADVISORY ON INTX 2012.pdf

See highlighted below; I have a call schedule with Mark Smith of the Da Vinci Group tmrw to discuss Alkermes & their addiction medications.

From: Mark R Smith [mailto:dvg@[redacted]
Sent: Thursday, October 02, 2014 10:01 AM
To: Pitcock, Josh
Cc: Karns, Allison
Subject: Re: Introduction

The Da Vinci Group

Thinking For the 21st Century

Washington Daily

Josh - Thank you as always. It was great to see you and the Governor earlier this week.

Allison - When you have a moment, please give me a call at 202[redacted] to discuss Alkermes and the work we are doing nationwide to prevent relapse to addiction to opioids and alcohol addiction in criminal justice settings through the use of the medication Vivitrol.

I would like to set up a meeting date with you and my mid-west based colleague from Alkermes, Adam Rondeau. Attached are some background materials on Vivitrol and a public policy directory on where we are using the medication in 75 programs in 23 states. I look forward to hearing from you and meeting you formally. All the best.

Regards,

Mark R. Smith

President

The Da Vinci Group

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On Sep 26, 2014, at 11:03 AM, Pitcock, Josh <jpitcock@sso.org> wrote:

Allison – I'd like to take a moment to introduce you to Mark Smith. Mark is with the Da Vinci Group and has several clients that operate in the public safety realm, including Alkermes. The governor and I saw Mark earlier this week and he mentioned that he would like to talk with you about Alkermes and their addiction medications. Mark is connected with Bruce Lemmon and previously had worked with Christina on this and some other issues. I hope you'll be able to connect and will let Mark take it from here in terms of following-up with you. Thanks. –Josh

Josh Pitcock

Federal Representative

State of Indiana

202-[redacted] (m)

202-624-1474 (o)

jpitcock@sso.org <mailto:jpitcock@sso.org>

# Alcohol Dependence Treatments: Comprehensive Healthcare Costs, Utilization Outcomes, and Pharmacotherapy Persistence

Onur Baser, MS, PhD; Mady Chalk, PhD; Richard Rawson, PhD; and David R. Gastfriend, MD


## Abstract

**Objectives:** To determine the healthcare costs associated with treatment of alcohol dependence with medications versus no medication and across the 4 medications approved by the US Food and Drug Administration (FDA).

**Study Design:** Retrospective claims database analysis.

**Methods:** Eligible adults with alcohol dependence were identified from a large US health plan and the IMS PharMetrics Integrated Database. Data included all medical and pharmacy claims at all available healthcare sites. Propensity score–based matching and inverse probability weighting were applied to baseline demographic, clinical, and healthcare utilization variables for 20,752 patients, half of whom used an FDA-approved medication for alcohol dependence. A similar comparison was performed among 15,502 patients treated with an FDA-approved medication: oral acamprosate calcium (n = 8958), oral disulfiram (n = 3492), oral naltrexone (NTX) hydrochloride (n = 2391), or extended-release injectable naltrexone (XR-NTX; n = 661). Analyses calculated 6-month treatment persistence, utilization, and paid claims for: alcoholism medications, detoxification and rehabilitation, alcohol-related and nonrelated inpatient admissions, outpatient services, and total costs.

**Results:** Medication was associated with fewer admissions of all types. Despite higher costs for medications, total healthcare costs, including inpatient, outpatient, and pharmacy costs, were 30% lower for patients who received a medication for their alcohol dependence. XR-NTX was associated with greater refill persistence and fewer hospitalizations for any reason and lower hospital costs than any of the oral medications. Despite higher costs for XR-NTX itself, total healthcare costs were not significantly different from oral NTX or disulfiram, and were 34% lower than with acamprosate.

**Conclusion:** In this largest cost study to date of alcohol pharmacotherapy, patients who received medication had lower healthcare utilization and total costs than patients who did not. XR-NTX showed an advantage over oral medications in treatment persistence and healthcare utilization, at comparable or lower total cost.


*(Am J Manag Care. 2011;17:S222-S234)*

For author information and disclosures, see end of text.

Alcohol consumption is the third leading actual cause of death in the United States[1]; however, among the top 25 diseases, patients with alcohol-use disorders are least likely to receive care that is based upon evidence-based practice.[2] The overall cost to the United States for alcohol-related illness was estimated at $184 billion in 1998[3]; payers spend an estimated $9.7 billion annually on direct treatment of these disorders.[4] Historically, over 70% of these costs has been spent by public systems[4]; however, this proportion is expected to increasingly shift to the private pay sector in coming years as a result of federal parity and health care legislative reform. With a national prevalence of alcohol dependence of 3.8%, or 7.9 million adults,[5] these morbidity, mortality, and cost burdens are driving efforts to develop the most clinically effective and resource-efficient evidence-based treatments possible.



The dominant mode of treatment of alcohol dependence is psychosocial treatment or counseling, and several models have shown evidence for effectiveness.[6] Although 4 medications have been approved by the US Food and Drug Administration (FDA) for the treatment of alcohol dependence, there is little adoption of these agents.[7,8] Survey results published in 2007 reported that pharmacotherapies for substance-use disorders (SUDs) were offered in less than 25% of public and private specialty treatment programs[7] and a 2007 study reported that SUD medications comprised less than 1% of all SUD treatment costs.[8] Nevertheless, the National Institute on Alcohol Abuse and Alcoholism has issued recommendations stating that medications are "helpful to patients in reducing drinking, reducing relapse to heavy drinking, achieving and maintaining abstinence, or a combination of these effects" and clinicians should "consider adding medication whenever [they] are treating someone with active alcohol dependence."[6]

There are multiple reasons why medication-assisted treatment (MAT) for alcohol dependence is not widely used, including long-standing traditions rooted in the mutual help movement, but adoption of MAT is also predicated on concerns about poor patient adherence to medication, modest efficacy, and poor cost-effectiveness.[9-11] Retrospective insurance database studies of oral medications have reported that 50% of patients fail to obtain their first refill,[12,13] and refill rates are worse for alcoholism medications

than for statins and psychiatric medications.[14] Clinical trials have found that medication adherence is crucial to efficacy.[15]

Medication adherence in substance-dependence treatment has been a priority concern of the National Institutes of Health for over 3 decades.[16] In 2006, the FDA approved the first extended-release formulation for the treatment of alcohol dependence, extended-release naltrexone (XR-NTX), which was designed to address the challenge of adherence through a once-monthly injection.[17] Of the 4 agents FDA-approved for the treatment of alcohol dependence studied in a retrospective claims analysis of commercial insureds, XR-NTX was associated with reduced estimated charges and utilization of inpatient detoxification days and alcoholism-related inpatient days, compared with all 3 oral agents (ie, oral naltrexone, disulfiram, and acamprosate calcium).[18] Given the importance of alcohol dependence treatment for public health and healthcare cost containment, the present study was designed to extend current knowledge of real-world effectiveness with alcohol dependence treatments, including treatment with no medication, any approved medication, and among the approved medications, treatment with each specific agent. This study sought to examine a larger cohort of insured patients treated with XR-NTX than previously studied, and to determine a comprehensive range of healthcare utilization and actual expended healthcare costs for each treatment category.

## Methods

### *Data Sources and Study Population*

This was a retrospective database analysis conducted using commercial enrollees from a large US health plan affiliated with i3 Innovus and the PharMetrics Integrated Database from 2005 to 2009. These databases included medical and pharmacy claims from all available healthcare sites (inpatient, hospital outpatient, emergency department [ED], physician's office, and surgery center) for virtually all types of provided services, including specialty, preventive office-based treatments, and retail and mail order pharmacy claims.

For the comparison of the "no medication" group to the "any medication" group, patients were required have at least 1 claim for alcohol dependence (*Diagnostic and Statistical Manual of Mental Disorders, 4th Edition,* code 303.xx) during the pre- or post-index period, have an alcohol use disorder diagnosis pre-index, and have at least 6 months of continuous enrollment pre-index and 6 months post-index. The earliest pharmacy claim for alcohol medication was set as the index date for the any medication group. The index date was defined as the first medical claim for a nonpharmacologic treatment such as a detoxification facility claim, a substance abuse treatment facility claim, or a substance abuse counseling claim. Patients in the nonpharmacologic substance group had no prescription fills for alcoholism medication while patients in the any medication group had at least 1 fill for any of the 4 alcoholism medications. Patients with liver failure during the pre-index period were excluded. Furthermore, patients were excluded if they had claims for pharmacological treatment in the month prior to the index date (with the exception of the XR-NTX group, because this group was occasionally required to demonstrate prior oral medication failure). These inclusion/exclusion criteria led to a final sample of 20,670 patients in the no medication group and 15,502 patients in the any medication group. **Figure 1** presents the sample sizes after applying the inclusion/exclusion criteria.

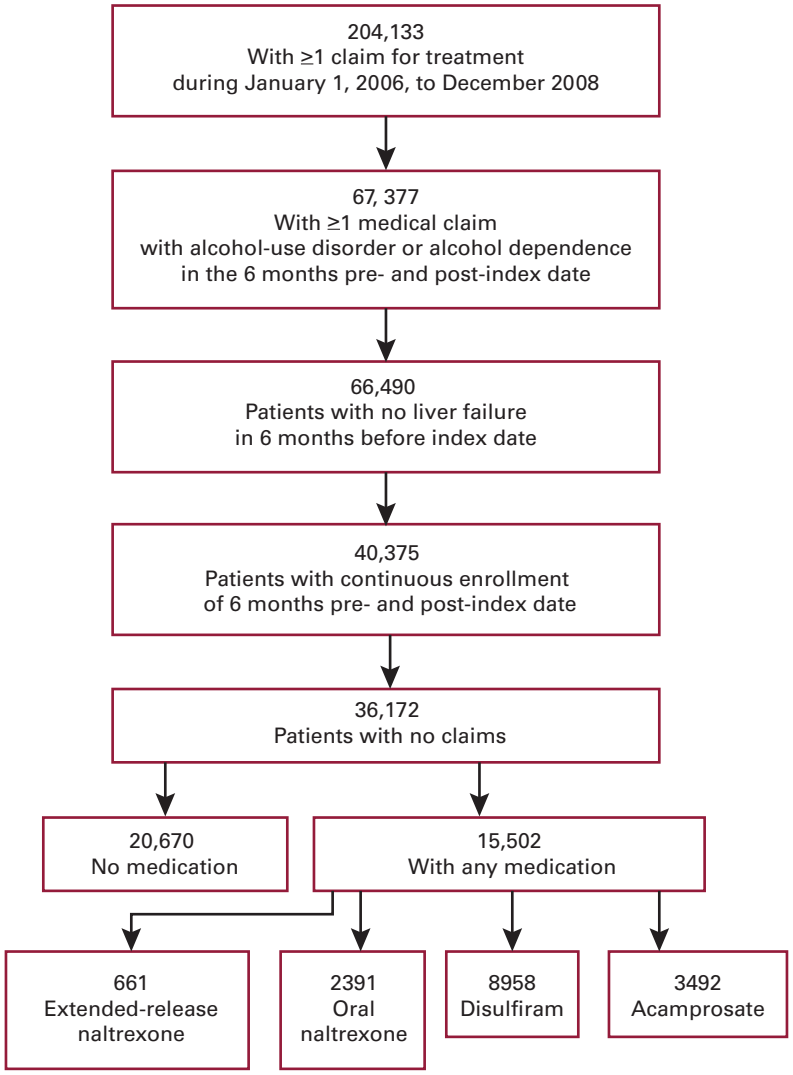
Similar criteria were required for patients in the comparison of the 4 alcoholism medications. Patients treated with XR-NTX were identified on the basis of an outpatient drug claim using the National Drug Code (NDC) or medical claims with the Healthcare Common Procedure Coding System code. The other medications, such as oral naltrexone, disulfiram, or acamprosate were identified using outpatient drug claims based on NDCs. The final sample of 661 patients in the XR-NTX group, 2391 patients in the oral NTX group, 8958 patients in the disulfiram group, and 3492 patients in the acamprosate group, was identified after applying the inclusion/exclusion criteria.

### *Statistical Analysis*

We derived demographic and clinical characteristics of the study populations at baseline. In particular, age, sex, and geographic location were measured at the index date. Deyo-Charlson comorbidity score,[19] Elixhauser score,[20] and the number of distinct psychiatric diagnoses and medications were calculated during the pre-index period. The Deyo-Charlson comorbidity score is an *International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM)* code adaption of the Charlson index, which assigns a range of weights, from 1 to 6 according to disease severity, for 19 conditions. The Elixhauser score is also a claims-based comorbidity index which sums a patient's comorbid conditions from among 30 *ICD-9-CM* comorbidity flags, differentiating secondary diagnoses from comorbidities by using diagnosis-related groups.

For socioeconomic status (SES), we constructed a summary measure for each US Zone Improvement Plan (ZIP) code using data on income, education, and occupation from the 2000 US Census and then linked this information to the patient's ZIP code of residence in the analytic files.[21] Factor analysis was used to identify 6 census variables that could be

**Figure 1.** Patient Selection Process




meaningfully combined into a summary socioeconomic status score. These variables included 3 measures of wealth/income (median household income, median value of housing units, and proportion of households with interest, dividend, or rental income), 2 measures of education (proportion of adult residents completing high school and college), and 1 measure of occupation/employment (proportion of employed residents with management, professional, and related occupations).[22]

Healthcare utilization and costs were calculated during both the pre-index and post-index periods. In terms of inpatient utilization, the number of detoxification facility days, and the number of detoxification and/or rehabilitation (admissions with an *ICD-9-CM* procedure for detoxification or rehabilitation), alcohol (admission with a principal diagnosis), and nonrelated inpatient admissions were measured. ED visits, alcohol-related physician visits, alcohol and substance abuse psychosocial provider visits, and non–alcohol-related outpatient visits were calculated. Utilization measures were presented per 1000 patients. Associated costs related to these measures and total costs were also calculated.

In addition to healthcare utilization and costs, we evaluated adherence by analyzing medication possession ratio and days of persistence with index medication refills post-index date.

Baseline characteristics were compared between the patient cohorts, and descriptive statistics were calculated as percentages and standard deviations. Differences between the cohorts were analyzed using the *t*-test, Mann-Whitney U test, and $\chi^2$ test, and standardized differences were calculated. It has been demonstrated that standardized differences 10% and higher between the baseline variables are significant, and need to be adjusted to compare the outcome measures among the groups.[23,24]

Propensity-score matching was applied to compare the risk-adjusted outcomes between the no medication group and the any medication group. Propensity-score matching is a technique that aims at adjusting for selection bias in nonexperimental, nonrandomized, and retrospective studies like the present one.[25] By using propensity-score matching, each patient in the any medication group was "mirrored" by a patient with similar predefined characteristics in the no medication group. The following characteristics were used to match: age, sex, region, comorbid scores, SES, baseline healthcare utilization, and costs. Logistic regression was used to estimate propensity scores. Several interaction variables were constructed, but they were not determined to be significant. Estimation power of the logistic regression was determined by C statistics. Following the guidelines set forth by Baser, it was determined that one-to-one matching created the best balance among the groups.[26]

Following Imbens and Lechner, we applied propensity-score matching that accounts for multilevel treatments when comparing the 4 alcoholism medication groups.[27,28] Several applications of this method are presented in the medical literature.[29-31] The first step uses multinomial logistic regression

**Table 1.** Risk-Adjusted Baseline Characteristics of Alcohol-Dependent Patients With Any Versus No Medication

| Pre-Index Period (6-month period before index date) | Alcohol-Dependent Patients (each group has N = 10,376) Any medication | No medication | |
|---|---|---|---|
| **Continuous variables** | **Mean (SD)** | **Mean (SD)** | ***P*** |
| **Healthcare utilization** | | | |
| **Pre-index number of detox facility days (number of days/1000 patients)** | 79 (938) | 65 (779) | .2366 |
| **Pre-index inpatient (number of admissions/1000 patients)** | | | |
| Detoxification and/or rehabilitation | 15 (147) | 14 (135) | .5553 |
| Alcohol-related inpatient admission | 139 (436) | 125 (427) | **.0244** |
| Non–alcohol-related inpatient admission | 264 (607) | 273 (632) | .2625 |
| **Pre-index outpatient (number of visits/1000 patients)** | | | |
| Emergency department visit | 734 (1968) | 778 (2149) | .1236 |
| Alcohol-related and physician provider | 774 (3835) | 487 (3110) | **<.0001** |
| Alcohol-related and substance abuse psychosocial provider | 521 (3797) | 374 (2585) | **.0011** |
| Non–alcohol-related outpatient admission | 10,602 (11,063) | 9846 (11,035) | **<.0001** |
| **Costs (per patient)** | | | |
| **Pre-index inpatient** | | | |
| Cost of detoxification and/or rehabilitation | $30 ($493) | $0 ($0) | **<.0001** |
| Cost of alcohol-related inpatient admission | $720 ($4315) | $650 ($3909) | .2224 |
| Cost of non–alcohol-related inpatient admission | $2059 ($8297) | $2545 ($10,659) | **.0002** |
| **Pre-index outpatient** | | | |
| Cost of emergency department visit | $207 ($693) | $244 ($850) | **.0006** |
| Cost of alcohol-related and physician provider | $94 ($731) | $72 ($817) | **.0403** |
| Cost of alcohol-related and substance abuse | $50 ($355) | $25 ($259) | **<.0001** |
| Cost of non–alcohol-related outpatient admission | $21 ($25) | $20 ($27) | **.0107** |
| **Pre-index pharmacy** | | | |
| Cost of FDA-approved alcohol dependence medications | $5 ($45) | $0 ($0) | **<.0001** |
| Cost of other psychiatric medications | $122 ($427) | $62 ($307) | **<.0001** |
| Cost of nonpsychiatric medications | $361 ($899) | $247 ($806) | **<.0001** |
| **Total cost (per patient = inpatient + outpatient + pharmacy)** | $5922 ($11,439) | $6174 ($13,726) | .1519 |

FDA indicates US Food and Drug Administration.

to estimate conditional probabilities of being in the particular treatment group. The second and final step estimates conditional expectation of outcome given the treatment level. Adjusted Wald tests were performed to test for the difference in weighted characteristics across the treatment cohorts.

Statistical analyses were performed using SAS v9.2 (SAS Institute, Cary, North Carolina) and STATA v10 (Stata Corp, College Station, Texas).

## Results

The risk-adjusted pre-index characteristics of 10,376 patients matched between each of the 2 groups (any medication and no medication, respectively) showed the following similarities: age, (44.4 vs 44.5 years; *P* = not significant [NS]); sex (male, 61.8% vs 61.9%; *P* = NS); geographic region (Eastern, 18.4% vs 18.0%; *P* = NS); SES score (high SES, 29.2% vs 29.2%; *P* = NS); and pre-index severity (proxied by having a ≥3 Elixhauser Index score, 25.2% vs 25.1%; *P* = .06). Differences in the Deyo-Charlson comorbidity score (0.34 vs 0.38; *P* =.0002) and Elixhauser Comorbid conditions (1.63 vs 1.57; *P* = .0034) were significant, but in opposite directions. During the pre-index period, the number of distinct psychiatric diagnoses and medications were higher in patients in the any medication group compared with the no

medication group (2.71 vs 2.32 and 1.68 vs 1.29, respectively; both $P$ <.0001).

Table 1 shows that, on average, detoxification admissions per 1000 patients in the any medication and no medication groups were similar (15 vs 14, respectively). Outpatient visits were significantly higher for patients in the any medication group. In particular, per 1000 patients, alcohol-related physician provider visits (774 vs 487) and non–alcohol-related outpatient visits (10,602 vs 9846) were significantly higher for the any medication group than the no medication group. The largest driver of pre-index treatment costs, however, was the cost of non–alcohol-related inpatient admission ($2059 vs $2545 per patient). After risk adjustment, the baseline costs in the any medication group were $5922 per patient versus $6174 per patient in the no medication group.

Table 2 presents the risk-adjusted outcome results. Patients in the no medication group stayed more days in detoxification facilities post-index relative to patients in the any medication group (3497 vs 483 days per 1000 patients). They had significantly more psychiatric diagnoses during the post-index period (3.19 vs 3.07). Post-index detoxification and/or rehabilitation admissions (563 vs 85), alcohol (660 vs 202), and nonalcohol (407 vs 257) admissions were significantly higher per 1000 patients in the no medication group. Higher admission days for the no medication group in detoxification and/or rehabilitation translated to a cost burden of $1350 versus $209 per patient in the any medication group. Costs for alcohol-related admissions were $2464 versus $801, and $2751 versus $2336 for non–alcohol-related inpatient admissions, respectively.

The pattern of greater utilization and costs also existed among patients in the no medication group for outpatient visits. This group was more likely to have physician provider visits (1970 vs 1454), psychosocial provider visits (1740 vs 991), and non–alcohol-related outpatient visits (14,101 vs 13,349) per 1000 patients. This translated into a greater cost burden of $106 per patient due to more physician provider visits and $61 due to more psychosocial provider visits. The 6-month total healthcare cost for a patient in the no medication group was $11,677 versus $8134 in the any medication group.

Among 15,502 patients who used any pharmacologic drug, 661 patients were treated with XR-NTX, 2391 with oral NTX, 3492 with disulfiram, and 8958 with acamprosate. Patients in the XR-NTX group were slightly older (45.91 years vs 44.24, $P$ <.001; 43.53, $P$ <.0001; 45.63, $P$ = NS, respectively). There were no differences in the percentages of males in the groups (60% vs 58%, 62%, 59%; all $P$ = NS). However, patients given XR-NTX resided more commonly in the East (34.0% vs 26%, 16%, 18%; all $P$ <.0001) and South (31% vs 19%, 16%, 26%; all $P$ <.01) compared with the Midwest and West. There was no clear pattern of SES differences among the 4 groups.

Table 3 presents the pre-index clinical, utilization, and cost characteristics of the 4 alcohol medication groups. In terms of severity (proxied by percentage with a ≥3 Elixhauser score) the XR-NTX group (31.0%) did not differ in high comorbidity rates relative to oral NTX (34.5%) or disulfiram (28.4%), but it was significantly lower compared with those given acamprosate (37.9%, $P$ = .0004). However, patients in the XR-NTX group had a higher use of distinct psychiatric medication relative to the other groups. Compared with patients in the XR-NTX cohort, during the pre-index period, those receiving acamprosate had significantly more detoxification facility days, and those given disulfiram had significantly fewer. Also, the acamprosate group had more detoxification and/or rehabilitation admissions and alcohol- and non–alcohol-related admissions compared with those in the XR-NTX group. During the pre-index period, the number of non–alcohol-related outpatient visits was significantly higher in the XR-NTX group relative to others.

The total healthcare costs were significantly higher for patients in the XR-NTX group compared with those in the oral NTX and the disulfiram groups, but there were no differences in pretreatment costs between XR-NTX and acamprosate.

After adjusting for these baseline differences, the risk-adjusted outcome results for the 4 groups are presented in Table 4. Patients receiving XR-NTX had significantly higher refill adherence rates than patients in the other groups (21% vs 11% for oral NTX, 9% for disulfiram, and 6% for acamprosate). The number of persistence days was also significantly higher (61.6 days vs 49.8 days with oral naltrexone, 45.8 days with disulfiram, and 42.6 days with acamprosate) (Figure 2A). Patients receiving XR-NTX had a significantly lower number of distinct diagnoses relative to those given acamprosate (3.05 vs 3.30), and a lower number of psychiatric medications relative to those given disulfiram (1.96 vs 2.80).

Inpatient healthcare utilization in the XR-NTX group was significantly lower than that in the other groups. Patients given XR-NTX spent significantly fewer days in a detoxification facility relative to those given disulfiram or acamprosate (227 days vs 429 days vs 741 days per 1000 patients, respectively). Detoxification and/or rehabilitation admission and alcohol- and non–alcohol-related admission were significantly lower in the XR-NTX group relative to the other groups ($P$ <.01) (Figure 2B). This translated

**Table 2.** Risk-Adjusted Outcomes in Alcohol-Dependent Patients With Any Versus No Medication

| Post-Index Period (6 months after index date) | Alcohol-Dependent Patients (each group has N = 10,376) | | |
|---|---|---|---|
| | Any medication | No medication | |
| **Outcome** | **Mean (SD)** | **Mean (SD)** | ***P*** |
| **Post-index number of distinct psychiatric diagnoses** | 3.07 (1.78) | 3.19 (1.71) | **<.0001** |
| **Post-index number of distinct psychiatric medication** | 2.25 (1.83) | 1.39 (1.56) | **<.0001** |
| **Healthcare utilization** | | | |
| **Post-index number of detoxification facility days (number of days/1000 patients)** | 483 (2489) | 3497 (7293) | **<.0001** |
| **Post-index inpatient (number of admissions/1000 patients)** | | | |
| Detoxification and/or rehabilitation | 85 (336) | 563 (641) | **<.0001** |
| Alcohol-related inpatient admission | 202 (562) | 660 (863) | **<.0001** |
| Non–alcohol-related inpatient admission | 257 (650) | 407 (757) | **<.0001** |
| **Post-index outpatient (number of visits/1000 patients)** | | | |
| Emergency department visit | 787 (2352) | 648 (2169) | **<.0001** |
| Alcohol-related and physician provider | 1454 (5266) | 1970 (6064) | **<.0001** |
| Alcohol-related and substance abuse psychosocial provider | 991 (4425) | 1740 (5781) | **<.0001** |
| Non–alcohol-related outpatient | 13,349 (12,919) | 14,101 (14,126) | **.0007** |
| **Costs (per patient)** | | | |
| **Post-index inpatient** | | | |
| Cost of detoxification and/or rehabilitation | $209 ($1140) | $1350 ($2863) | **<.0001** |
| Cost of alcohol-related inpatient admission | $801 ($3749) | $2464 ($7025) | **<.0001** |
| Cost of non–alcohol-related inpatient admission | $2336 ($12,492) | $2751 ($13,815) | **<.0001** |
| **Post-index outpatient** | | | |
| Cost of emergency department visit | $207 ($744) | $173 ($695) | **<.0001** |
| Cost of alcohol-related physician provider | $199 ($988) | $305 ($1204) | **<.0001** |
| Cost of alcohol-related substance abuse psychosocial provider | $87 ($440) | $148 ($605) | **<.0001** |
| Cost of non–alcohol-related | $25 ($29) | $27 ($32) | .0592 |
| **Post-index pharmacy** | | | |
| Cost of FDA-approved alcohol dependence medications | $350 ($637) | $1 ($17) | **<.0001** |
| Cost of other psychiatric medications | $228 ($677) | $95 ($427) | **<.0001** |
| Cost of nonpsychiatric medications | $523 ($1153) | $291 ($967) | **<.0001** |
| **Total cost (per patient = inpatient + outpatient + pharmacy)** | $8134 ($15,887) | $11,677 ($19,889) | **<.0001** |

FDA indicates US Food and Drug Administration.

to lower inpatient costs per patient for detoxification and rehabilitation (XR-NTX: $105 vs $192 with oral NTX, $203 with disulfiram, and $288 with acamprosate), alcohol-related inpatient admission (XR-NTX: $474 vs $618 with oral NTX, $874 with disulfiram, and $1166 with acamprosate), and non–alcohol-related admission (XR-NTX: $730 vs $1091 with oral naltrexone, $1498 with disulfiram, and $3885 with acamprosate).

Although outpatient healthcare utilization was similar across the groups, the average patient receiving XR-NTX had higher 6-month costs for ED visits ($272) vs oral agents ($227 with oral naltrexone, $227 with disulfiram, and $209 with acamprosate), and lower costs for alcohol-related physician provider visits (XR-NTX: $67 vs $107 oral NTX, $118 with disulfiram, and $291 with acamprosate) and alcohol and substance abuse outpatient visits (XR-NTX: $46 vs $76 with oral NTX, $114 with disulfiram, and $82 with acamprosate). XR-NTX was associated with higher costs for non–alcohol-related outpatient visits (NXT-XR: $4510 vs $3444 with oral NTX, $3194 with disulfiram, and $3589 with acamprosate).

**Table 3.** Baseline Characteristics of Alcohol-Dependent Patients by Pharmacotherapy

| Pre-Index Period (6-month period before index date) | XR-NTX (n = 661) |
|---|---|
| **Continuous variables** | **Mean (SD)** |
| **Clinical characteristics** | |
| Pre-index Deyo-Charlson comorbidity score | 0.41 (0.91) |
| Pre-index Elixhauser comorbid conditions | 1.91 (1.71) |
| Pre-index number of distinct psychiatric diagnoses | 3.20 (1.89) |
| Pre-index number of distinct psychiatric medication | 2.00 (1.79) |
| **Healthcare utilization** | |
| Pre-index number of detoxification facility days number of days/1000 patients) | 1212 (3802) |
| **Pre-index inpatient (number of admissions/1000 patients)** | |
| Detoxification and/or rehabilitation | 215 (536) |
| Alcohol-related inpatient admission | 380 (840) |
| Non–alcohol-related inpatient admission | 333 (766) |
| **Pre-index outpatient (number of visits/1000 patients)** | |
| Emergency department visits | 911 (2234) |
| Alcohol-related and physician provider | 773 (3785) |
| Alcohol-related and substance abuse psychosocial provider | 490 (2465) |
| Non–alcohol-related outpatient | 12,470 (12,239) |
| **Costs (per patient)** | |
| **Pre-index inpatient** | |
| Cost of detoxification and/or rehabilitation | $688 ($2344) |
| Cost of alcohol-related inpatient admission | $1638 ($6032) |
| Cost of non–alcohol-related inpatient admission | $2504 ($8362) |
| **Pre-index outpatient** | |
| Cost of emergency department visits | $244 ($700) |
| Cost of alcohol-related and physician provider | $82 ($468) |
| Cost of alcohol-related and substance abuse psychosocial provider | $53 ($329) |
| Cost of non–alcohol-related | $25 ($27) |
| **Pre-index pharmacy** | |
| Cost of FDA-approved alcohol dependence medications | $100 ($174) |
| Cost of other psychiatric medications | $163 ($486) |
| Cost of nonpsychiatric medications | $553 ($1436) |
| **Total cost (per patient = inpatient + outpatient + pharmacy)** | $9467 ($13,988) |

FDA indicates US Food and Drug Administration; NTX, naltrexone; XR-NTX, extended-release injectable naltrexone.

Post-index pharmacy costs were higher for the XR-NTX group; cost savings from inpatient and outpatient admissions, however, resulted in total costs that were significantly lower in patients given XR-NTX compared with those given acamprosate ($6757 vs $10,345 per patient). Significant differences in overall costs were not observed among the NXT-XR group and other groups.

## Discussion

Access to the combined data from these 2 large insurance data sets allowed for the examination of clinical outcomes and costs/benefits associated with available types of alcoholism treatments (as employed in the US healthcare system), resulting in the largest health economic evaluation of alcoholism treatments reported to date in the literature.

| Alcohol-Dependence Pharmacotherapy | | | | | |
|---|---|---|---|---|---|
| Oral NTX (n = 2391) | | Disulfiram (n = 3492) | | Acamprosate (n = 8958) | |
| Mean (SD) | *P* | Mean (SD) | *P* | Mean (SD) | *P* |
| 0.33 (0.82) | **.0280** | 0.33 (0.92) | **.0233** | 0.40 (0.97) | .7860 |
| 2.04 (1.73) | .0850 | 1.74 (1.71) | **.0262** | 2.17 (1.75) | **.0001** |
| 3.14 (1.92) | .4632 | 2.91 (1.96) | **.0004** | 3.08 (1.84) | .1228 |
| 1.78 (1.68) | **.0055** | 1.73 (1.67) | **.0003** | 1.70 (1.64) | **<.0001** |
| 1376 (4169) | .3375 | 803 (2805) | **.0086** | 1644 (3956) | **.0051** |
| 226 (525) | .6384 | 165 (463) | **.0253** | 294 (529) | **.0003** |
| 350 (642) | .3997 | 313 (704) | .0553 | 469 (685) | **.0078** |
| 377 (686) | .1775 | 297 (653) | .2553 | 412 (735) | **.0107** |
| 810 (2055) | .2954 | 840 (2209) | .4560 | 772 (1993) | .1207 |
| 622 (3155) | .3486 | 1009 (4657) | .1582 | 657 (3346) | .4420 |
| 410 (5661) | .5933 | 782 (3643) | **.0107** | 347 (2187) | .1468 |
| 11,359 (11,964) | **.0381** | 10,877 (11,930) | **.0021** | 10,757 (10,804) | **.0005** |
| $571 ($2000) | .2407 | $313 ($1275) | **.0001** | $708 ($1890) | .8334 |
| $1360 ($4333) | .2669 | $1056 ($4452) | **.0183** | $1660 ($5759) | .9304 |
| $2476 ($7975) | .9396 | $2420 ($19,299) | .8555 | $2619 ($9331) | .7336 |
| $252 ($789) | .8013 | $266 ($990) | .5018 | $225 ($740) | .5050 |
| $86 ($602) | .8563 | $122 ($743) | .0740 | $91 ($773) | .6581 |
| $38 ($312) | .2870 | $89 ($506) | **.0203** | $35 ($312) | .1620 |
| $23 ($25) | **.0273** | $22 ($29) | **.0040** | $22 ($25) | **.0017** |
| $0 ($0) | **<.0001** | $0 ($0) | **<.0001** | $0 ($0) | **<.0001** |
| $145 ($525) | .4096 | $109 ($394) | **.0069** | $114 ($398) | **.0118** |
| $373 ($854) | **.0021** | $308 ($838) | **<.0001** | $360 ($858) | **.0007** |
| $8031 ($12,113) | **.0165** | $6904 ($21,495) | **.0001** | $9543 ($118,914) | .9556 |

This risk-adjusted analysis compared 20,752 patients who received any versus no medication, and 15,502 patients who received 1 of the 4 FDA-approved medications. A total of 661 patients received treatment with XR-NTX, making this the largest sample studied to date with this particular treatment. In addition, the study involved a comprehensive analysis of actual total healthcare costs paid and healthcare service utilization. Results showed that, compared with alcohol dependence treatment that did not include medication, medication-assisted treatment was associated with significantly fewer admissions for detoxification and/or rehabilitation, alcohol-related inpatient medical care, and non–alcohol-related inpatient medical care. Costs for services in all of these inpatient categories were significantly lower in

**Table 4.** Risk-Adjusted Outcome Measures in Alcohol-Dependent Patients by Pharmacotherapy

| | Alcohol-Dependence Pharmacotherapy | | | | | | |
|---|---|---|---|---|---|---|---|
| **Post-Index Period (6 months after index date)** | **XR-NTX (n = 661)** | **Oral NTX (n = 2391)** | | **Disulfiram (n = 3492)** | | **Acamprosate (n = 8958)** | |
| **Compliance and persistence with therapy** | **%** | **%** | ***P*** | **%** | ***P*** | **%** | ***P*** |
| Continuous MPR ≥0.8 | 21 | 11 | **<.0001** | 9 | **<.0001** | 6 | **<.0001** |
| **Outcome** | **Mean** | **Mean** | ***P*** | **Mean** | ***P*** | **Mean** | ***P*** |
| Persistence days with index medication | 61.65 | 49.75 | **.00** | 45.81 | **.00** | 42.56 | **.00** |
| Post-index number of distinct psychiatric diagnoses | 3.05 | 2.94 | .20 | 3.04 | .89 | 3.30 | **.04** |
| Post-index number of distinct psychiatric medications | 1.96 | 1.98 | .78 | 2.80 | **.00** | 2.10 | .20 |
| **Healthcare utilization** | | | | | | | |
| Post-index number of detoxification facility days (number of days/1000 patients) | 227 | 361 | .1442 | 429 | **.0472** | 741 | **.0039** |
| **Post-index inpatient (number of admissions/1000 patients)** | | | | | | | |
| Detoxification and/or rehabilitation | 43 | 76 | **.0039** | 98 | **.0001** | 120 | **.0001** |
| Alcohol-related inpatient admission | 82 | 184 | **<.0001** | 268 | **<.0001** | 317 | **<.0001** |
| Non–alcohol-related inpatient admission | 109 | 205 | **<.0001** | 250 | **<.0001** | 343 | **<.0001** |
| **Post-index outpatient (number of visits/1000 patients)** | | | | | | | |
| Emergency department visits | 903 | 817 | .5017 | 823 | .5604 | 809 | .5742 |
| Alcohol-related and physician provider | 1053 | 1154 | .7007 | 1140 | .7543 | 1678 | .1733 |
| Alcohol-related and substance abuse psychosocial provider | 705 | 999 | .1940 | 1171 | .0825 | 805 | .6922 |
| Non–alcohol-related outpatient | 14,414 | 12,726 | **.0086** | 13,159 | .0696 | 14,429 | .9868 |
| **Cost (per patient)** | | | | | | | |
| **Post-index inpatient** | | | | | | | |
| Cost of detoxification and/or rehabilitation | $105 | $192 | **<.0001** | $203 | **<.0001** | $288 | **<.0001** |
| Cost of alcohol-related inpatient admission | $474 | $618 | **<.0001** | $874 | **<.0001** | $1166 | **<.0001** |
| Cost of non–alcohol-related inpatient admission | $730 | $1091 | **<.0001** | $1498 | **<.0001** | $3885 | **<.0001** |
| **Post-index outpatient** | | | | | | | |
| Cost of emergency department visits | $272 | $227 | **.0007** | $227 | **.0011** | $209 | **.0001** |
| Cost of alcohol-related and physician provider | $67 | $107 | **<.0001** | $118 | **<.0001** | $291 | **<.0001** |
| Cost of alcohol-related and substance abuse psychosocial provider | $46 | $76 | **<.0001** | $114 | **<.0001** | $82 | **<.0001** |
| Cost of non–alcohol-related | $4510 | $3444 | **<.0001** | $3194 | **<.0001** | $3589 | **.0008** |
| **Post-index pharmacy** | | | | | | | |
| Cost of FDA-approved alcohol dependence medications | $2230 | $200 | **<.0001** | $209 | **<.0001** | $292 | **<.0001** |
| Cost of other psychiatric medications | $326 | $232 | **<.0001** | $168 | **<.0001** | $229 | **<.0001** |
| Cost of nonpsychiatric medications | $600 | $477 | **<.0001** | $417 | **<.0001** | $537 | .1160 |
| **Total cost (per patient = inpatient + outpatient + pharmacy)** | $6757 | $6595 | .6431 | $7107 | .3601 | $10,345 | **<.0001** |

FDA indicates US Food and Drug Administration; MPR, medication possession ratio; NTX, naltrexone; XR-NTX, extended-release injectable naltrexone.

patients who received a medication, and (despite significantly higher costs for medications) total healthcare costs, including inpatient, outpatient, and pharmacy costs, were 30% lower for patients who received a medication for their alcohol dependence. With XR-NTX, cost data associated with hospital admissions and stays reflected a similar picture. Hospital costs for patients receiving XR-NTX were significantly and substantially lower than those for patients receiving 1 of the 3 oral medications. Patients given XR-NTX used fewer days in detoxification and had fewer admissions to the hospital for any reason than patients given 1 of the 3 oral medications.

Costs for services in all of these inpatient categories were significantly lower for patients who received XR-NTX, and despite significantly higher costs for XR-NTX, total healthcare costs, including inpatient, outpatient, and pharmacy costs, were not significantly different from total costs with oral NTX or disulfiram, and were 34% lower than with acamprosate.

The frequency of hospital admission is an intensive utilization and cost-related variable and may also represent a proxy for morbidity, in the absence of direct clinical data (which is lacking with retrospective claims data such as these). As such, reduced hospitalization, which is obviously important in cost reduction, is also an important objective in its own right. For example, medication was associated with 30% lower costs than no medication treatment; compared with no medication treatment, the relative risk reduction associated with medication was 85% for admission to detoxification or rehabilitation, and 69% for alcohol-related admission. Among the 4 medications, total costs with XR-NTX were not significantly different from oral NTX and disulfiram, and they were 34% lower than those with acamprosate. XR-NTX was associated with relative risk reductions for admission to detoxification/rehabilitation of 43% versus oral NTX, 56% versus disulfiram, and 64% versus acamprosate, and reductions for admission to alcohol-related hospitalization of 55% versus oral NTX, 69% versus disulfiram, and 74% versus acamprosate.

These reductions showed an inverse association with refill persistence (Figure 2A). One of the most important challenges in the use of alcohol pharmacotherapies is retaining patients in treatment (on medication) for clinically adequate durations. In the 2 measures of treatment duration, participants receiving XR-NTX were retained significantly longer and more continuously on medication than participants receiving oral medications. Of the 4 agents, the 2 compliance parameters, persistence (days with index medication) and continuous mean possession ratio greater than 80% of days, both showed a similar pattern (in increasing order of persistence): acamprosate, disulfiram, oral NTX, and XR-NTX. This pattern closely follows the burden of medication administration: acamprosate, 2 tablets 3 times daily; disulfiram and oral NTX, 1 tablet once daily (oral NTX is sometimes given in higher doses every other day); and XR-NTX, 1 injection per month. Also, the pattern of persistence is opposite the rate of admissions with the 4 medications (Figure 2B).

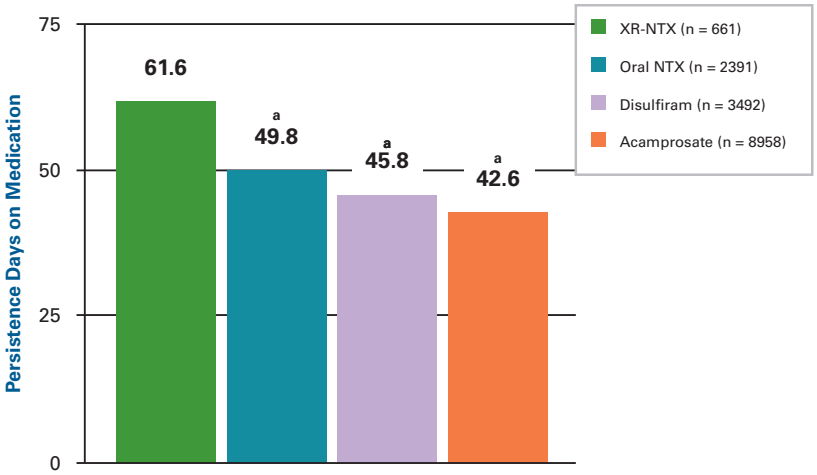
The cost differences found in these comparisons are revealing, because the group treated with any medication had overall medication costs that were more than double the medication costs (ie, nonalcoholism medications) of those with no alcoholism medications. Yet, their total healthcare costs were less. Similarly, the cost of XR-NTX alone was up to 10-fold higher than that for the oral alcohol dependence agents (some of which are available as generic products). Total healthcare costs, however, were either associated with no difference or lower expense. This finding suggests that the cost of a particular treatment should not be confused with the overall cost of care and that the overall objective of quality and efficient healthcare needs to transcend the compartmentalization of costs within pharmacy benefit management versus overall healthcare management.

These patients, in general, also had psychiatric and other medical comorbidities. The reasons for the higher cost of psychiatric and other medication are not clear. Physicians who use alcoholism pharmacotherapies may be more familiar with appropriate diagnosis and treatment of concurrent psychiatric and medical conditions. Also, because the any medication group spent less time in the hospital, effective outpatient management may have necessitated more aggressive use of outpatient medications.

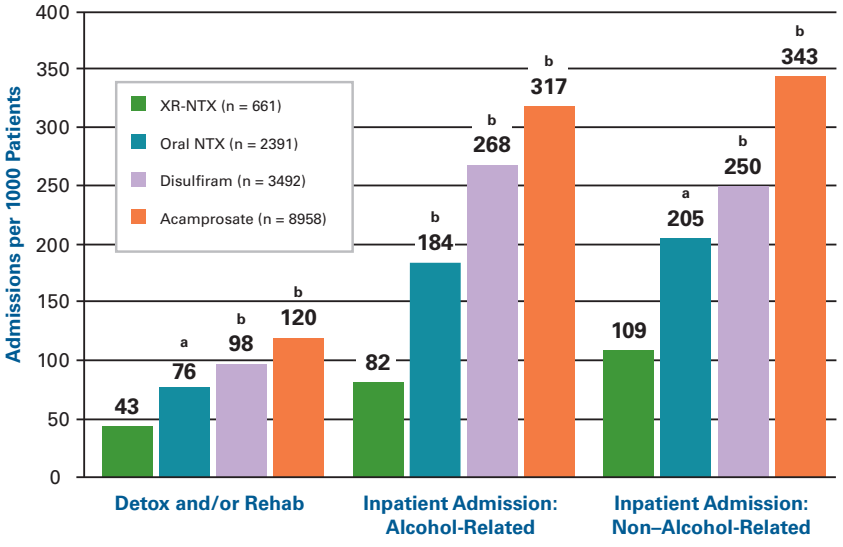
Retrospective claims analyses such as these have a number of limitations. Because the study design did not include random assignment to the any versus no medication conditions, nor to specific medication conditions, the findings represent associations, but not necessarily causality. The cohorts may have had unobserved differences in baseline characteristics; for example, patient motivation or healthcare service quality (eg, physician knowledge and training, psychosocial treatment methods used), so that the precise contribution of medication or type of medication cannot be definitively determined. Because there were no quantitative measures of baseline alcohol use, comparability of the participants' alcohol-use disorder severity across treatment conditions could not be ensured. Similarly, the absence of these baseline data make it impossible to compare reduction in alcohol quantity or frequency across conditions, a commonly used outcome measure in treatment outcome research. No data

**Figure 2.** Alcohol Dependence Pharmacotherapies: Health Economic Outcomes 6 Months After Index Date

**A.** Persistence Days on Medication




**B.** Inpatient Admissions per 1000 Patients




NTX indicates naltrexone; XR-NTX, extended-release injectable naltrexone.
[a] $P < .01$ vs XR-NTX.
[b] $P < .001$ vs XR-NTX.

are available regarding adverse events, which are important considerations, given that medications are known to have side effects, some of which are associated with boxed warnings on the prescribing information, and these differ between the oral and the injectable agents. Also, the time frame for outcomes was limited to 6 months and the samples consisted of commercial insureds as opposed to Medicaid or uninsured patients. Furthermore, the XR-NTX sample was smaller than the others (because it is the most recently introduced agent), subject inclusion was limited to patients with 1 year of continuous enrollment (which could omit those who lost insurance due to job loss), no information was available as to the recommended or adequate duration of treatment, and oral medication adherence was only indirectly measured through

prescription refills (therefore no information was available to confirm that patients took their oral medications).

Despite these limitations, the study has some relevant strengths. Baseline data (Table 2), with propensity-score matching and inverse probability weighting across a number of demographic, clinical, and utilization variables, demonstrated good comparability between the any versus no medication cohorts. The analysis showed robust findings in healthcare cost and utilization domains, a major strength that mitigates the limitation of not having alcohol consumption data. Although the average treatment duration was 2 to 3 months, meaningful outcomes were detected over a 6-month time frame, indicating that treatment benefits may outlast the active treatment phase. The patterns observed with medication adherence, hospital utilization, and costs demonstrated a high degree of internal consistency. External validity was also strong, given the relatively large sample sizes composed of real-world patients treated by community providers and given conventional treatment.

These findings are compatible with real-world evaluations of alcohol pharmacotherapy refill persistence.[12-14,17] Three prior analyses of pharmacy claims for oral NTX refills have shown that as few as half of patients obtain the first refill, and most do not complete a reasonable course of treatment.[12-14] One of these studies found significantly lower refill rates for oral alcohol pharmacotherapies than for statins, antidepressants, and antipsychotics,[14] and another found that refill failure was associated with significantly more detoxifications and hospital admissions.[13]

More recently, a retrospective claims analysis in NJ Blue Cross Blue Shield insureds found that although medication persistence remains an issue, XR-NTX was associated with significant reductions in cost due to alcohol-related hospitalizations, total medical costs, and total pharmacy costs (see the article by Jan et al in this supplement).[32] A study of AETNA beneficiaries showed that patients given XR-NTX persisted with treatment longer than those given oral medications, and XR-NTX was associated with decreased inpatient and emergency healthcare costs and utilization to a greater extent than patients receiving 1 of the 3 oral agents (see the article by Bryson et al in this supplement).[33]

Mark et al also analyzed retrospective commercial claims between any versus no medication, and among the 4 FDA-approved alcoholism medications. They determined that medication was associated with less detoxification and alcoholism-related inpatient care. That study also showed a similar pattern among the 4 medications; increased burden of medication administration (acamprosate >oral NTX or disulfiram >XR-NTX) was associated with decreased refill persistence. The XR-NTX cohort used 224 detoxification days per 1000 patients (vs 227 in the present study) and was associated with the fewest days for detoxification or alcohol-related hospitalizations among the 4 agents.[18] The present study replicates those findings and extends them, because the earlier study consisted of a single data source (examining 5954 matched cases in the any vs no medication comparison and 295 patients given XR-NTX) and used estimated charges and calculated these for only detoxification and alcohol-related inpatient admissions, whereas the present study combined 2 large data sources (examining 20,752 overall cases and 661 patients given XR-NTX) and calculated actual expended dollars for all healthcare costs, including the costs of the agents.

The relationships between use of medications, counseling, and utilization/cost outcomes suggested in these data are intriguing and raise important questions for further research. Although this study confined its cost evaluation to healthcare expenditures, society bears additional costs from alcohol dependence, due to deterioration, absenteeism and loss in the workforce, damage to property and life, and court proceedings and incarceration in the justice system. These costs are worthy of future analysis as well. Effectiveness findings with medication-assisted treatment that takes these aggregate burdens into account have led to implementation strategies in the public sector.[34] The National Quality Forum issued a statement in 2007 that "pharmacotherapy should be a standard component of treatment for SUD [substance use disorders]" [35] and efforts to increase pharmacotherapy use and design performance measures are under way.[36] Effective treatment with medication, and particularly the most effective pharmacologic therapy, is an opportunity that continues to warrant research, education, and implementation initiatives from healthcare systems, insurers, and policymakers.

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# Cost and Utilization Outcomes of Opioid-Dependence Treatments

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## Abstract

**Objectives:** To evaluate the healthcare costs associated with treatment of opioid-dependence disorder with medications versus no medication, and with the 4 agents approved by the US Food and Drug Administration (FDA).

**Study Design:** Retrospective claims database analysis.

**Methods:** Eligible adults with opioid dependence were identified from a large US health plan and the PharMetrics Integrated Database. Data included all medical and pharmacy claims at all available healthcare sites. Case-mix adjustment was applied using baseline demographic, clinical, and healthcare utilization variables for 13,316 patients; half of these patients used an FDA-approved medication for opioid dependence. A similar comparison was performed among 10,513 patients treated with extended-release naltrexone (NTX-XR) (n = 156) prior to FDA approval for opioid dependence or with a medication approved at the time: oral naltrexone (NTX) (n = 845), buprenorphine (n = 7596), or methadone (n = 1916). Analyses calculated 6-month persistence, utilization, and paid claims for opioid-dependence medications, detoxification and rehabilitation, opioid-related and non-related inpatient admissions, outpatient services, and total costs.

**Results:** Medication was associated with fewer inpatient admissions of all types. Despite higher costs for medications, total healthcare costs, including inpatient, outpatient, and pharmacy costs, were 29% lower for patients who received a medication for opioid dependence versus patients treated without medication. Patients given XR-NTX had fewer opioid-related and non–opioid-related hospitalizations than patients receiving oral medications. Despite higher costs for XR-NTX, total healthcare costs were not significantly different from those for oral NTX or buprenorphine, and were 49% lower than those for methadone.

**Conclusion:** Patients with opioid dependence who received medication for this disorder had lower hospital utilization and total costs than patients who did not receive pharmacologic therapy. Patients who received XR-NTX had lower inpatient healthcare utilization at comparable or lower total costs than those receiving oral medications.

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For author information and disclosures, see end of text.

Opioid-dependence disorder, or addiction, is a complex brain disease characterized by "uncontrollable drug craving, along with compulsive drug seeking and use that persist even in the face of devastating consequences."[1] In 2009, there were over 2 million opioid-dependent adults in the United States[2] and prescription opioid dependence has been increasing over the last 20 years due to growth in prescribing of high potency opioids for the treatment of pain. Drug overdose deaths now surpass gunshot deaths; in 16 states overdose deaths are more common than lethal car crashes, and drugged driving occurs at higher levels than alcohol-impaired driving.[3] Among those dependent upon heroin, it is estimated that more than 18 years of potential life are lost by age 65, with the leading causes of death being overdose, chronic liver disease, and accidents.[4] The cost of heroin dependence in the United States was estimated at $21 billion in 2000.[5]



There are 3 main classes of oral pharmacologic treatments for opioid dependence: opioid receptor agonists (methadone),[6] partial agonists (buprenorphine, buprenorphine/naloxone),[7] and antagonists (oral naltrexone [NTX]).[8] Agonist therapy is effective for a broad range of dependence consequences and outcomes, although diversion and abuse can be problematic.[9] Antagonist therapy (ie, oral NTX) is not abused; however, its clinical effectiveness has been limited by poor patient compliance with daily dosing,[10] leading the National Institute on Drug Abuse to call for a sustained-release antagonist preparation.[11] Extended-release naltrexone (XR-NTX)[12] was approved by the US Food and Drug Administration (FDA) in October 2010 for the treatment of alcohol dependence and the prevention of relapse to opioid dependence following detoxification.

Much of the population with opioid dependence remains untreated, due to obstacles including denial about the disease, poor motivation, stigma, limited insurance coverage, and limited access to care; factors that have been proposed to improve this situation include expanded access to opioid agonist treatment, treatment with a nonreinforcing "blocker," treatment in a conventional medical setting, and an approach that conforms to the abstinence model.[3,13-16]

Given the growing health and social burdens of opioid dependence and new formulations and approaches to treatment introduced in the past 10 years, the present study was designed to examine a comprehensive range of real-world healthcare costs and

utilization with available treatments, including treatment with no medication, treatment with any of the currently approved medications, and among the currently approved medications, treatment with each of the 4 agents.

## Methods

### *Data Sources and Study Population*

Health Insurance Portability and Accountability Act–compliant pharmacy and medical administrative claims data from a proprietary US health plan and the PharMetrics Integrated Database for calendar years 2005 through 2009 were used for this retrospective, longitudinal study. For the first source, data for approximately 14 million individuals was available in 2008. The PharMetrics Integrated Database includes 85 US health plans providing healthcare coverage to more than 10 million persons annually throughout the United States. These data sources are well validated and were chosen because they cover large numbers of patients across all parts of the United States.

The end points of the study were healthcare cost and utilization. Two different comparisons were conducted: (1) between treated patients with any medication versus no medication, and (2) among patients treated with medication, comparison of patients treated with (a) XR-NTX; (b) oral NTX; (c) buprenorphine (with or without naloxone); and (d) methadone. Patients treated with XR-NTX were identified on the basis of an outpatient drug claim from the National Drug Code (NDC) or medical claims from the Healthcare Common Procedure Coding System code (because it is the 1 agent administered with a procedure). The other medications were identified using outpatient drug claims based on NDCs.

For patients in the no medication group, the index date was defined as the first medical claim for a nonpharmacologic treatment, such as a detoxification facility claim, a substance abuse treatment facility claim, or a substance abuse counseling claim. The index date for the group with medication use was determined as the earliest pharmacy claim for opioid medication.

The database's study population included patients continuously enrolled in a commercial health plan for at least 1 year (6 months pre–index date and 6 months post–index date). Patients were required to have at least 1 claim for opioid dependence or opioid-use disorder (*International Classification of Diseases, 9th Revision, Clinical Modification* [*ICD-9-CM*] codes 304.0x, 304.7x) in the 6 months prior to the index date or on the index date. Patients were excluded from the analysis if they (1) had claims for pharmacologic treatment for opioid dependence in the 1 month prior to the index date for patients with claims for oral NTX, buprenorphine, methadone, or nonpharmacologic treatment on the index date; or (2) had claims with a diagnosis of acute hepatitis or liver failure in the 6 months pre-index. This later restriction was applied due to the varying hepatic safety profiles of the medications.[17-19] **Figure 1** details the patient cohorts.

### *Study Variables*

Patients' age, sex, and geographic region were determined from the claims record. Using a previously validated formula for socioeconomic status,[20] we constructed a summary measure of socioeconomic status for each US Zone Improvement Plan (ZIP) code using data on income, education, and occupation from the 2000 US Census, and then linked this information to the patients' ZIP code of residence in the analytic files.[21] Comorbid conditions were measured during the 6-month period before the index date and defined using the methods of Elixhauser[22] and Charlson[23] to produce a single score for use in multivariate models. The Deyo-Charlson comorbidity score is an *ICD-9* code adaption of the Charlson index, which assigns a range of weights, from 1 to 6 according to disease severity, for 19 conditions. The Elixhauser score is also a claims-based comorbidity index which sums a patient's comorbid conditions from among 30 *ICD-9-CM* comorbidity flags, differentiating secondary diagnoses from comorbidities by using diagnosis-related groups.

Costs were calculated using the actual patient claims for healthcare use in the matched cohort. They are measured during both the pre- and post-index periods. In addition to the overall costs, the costs of detoxification and/or rehabilitation visits, opioid- and non–opioid-related inpatient and outpatient visits and emergency department (ED) visits, opioid-related physician visits, and opioid and substance abuse psychosocial provider visits were calculated.

Healthcare utilizations are represented per 1000 patients and detailed similar to healthcare costs. Adherence and persistence were measured using medication possession ratio (MPR) and time from the index date until time of discontinuation. MPR was calculated as the ratio of days' supply of the index medication to total days in the observation period and it was corrected for inpatient events under the assumption that during hospitalization, medication is supplied by the facility. The date of discontinuation was defined by the run-out days supply of the last prescription filled prior to the gap in therapy.

### *Analyses*

Baseline characteristics were compared between patient cohorts and descriptive statistics were calculated as mean

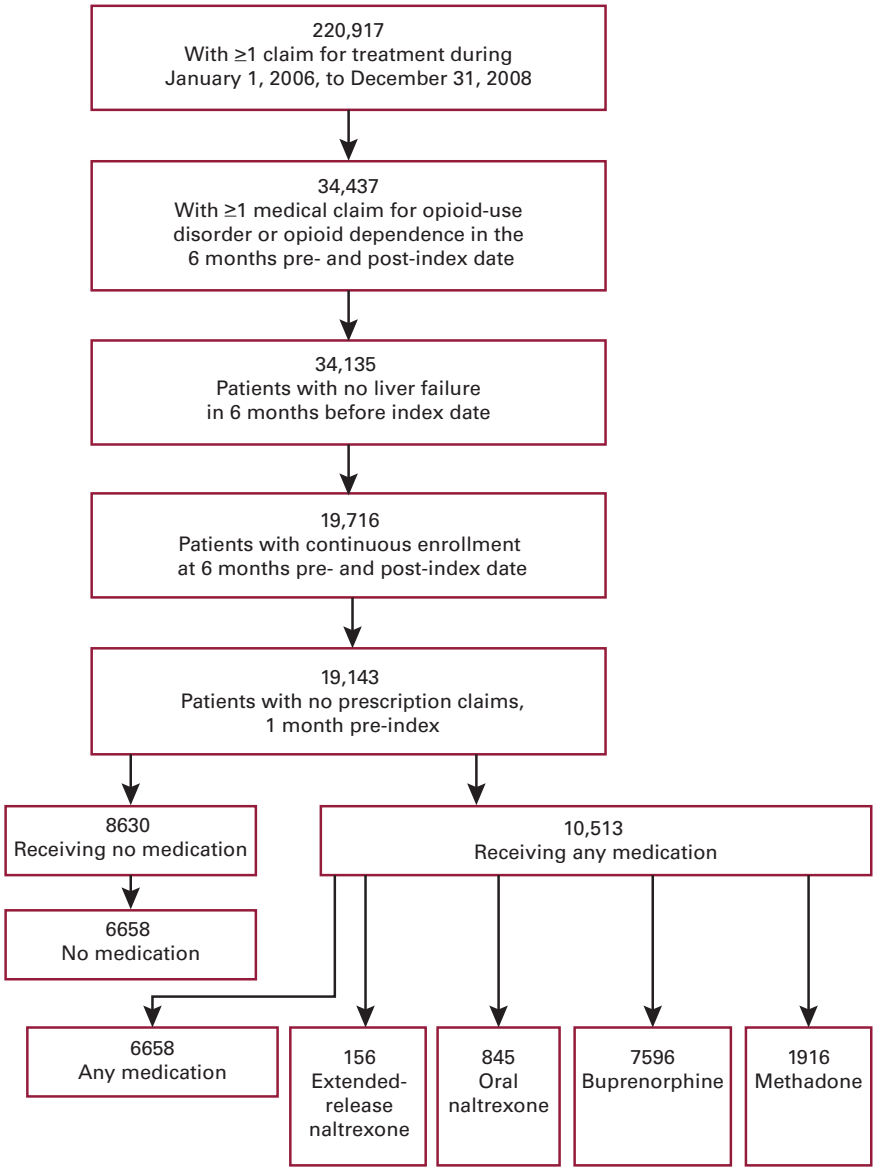
(standard deviation) and percentages. Differences between the cohorts were analyzed using the *t*-test, Mann-Whitney U tests, and $\chi^2$ tests.

A challenge to retrospective cohort studies in general—and to this study in particular—is the question of comparability of patient groups at the time of treatment initiation (ie, is the physician equally likely to choose between the treatment options, or rather is the choice of treatment based on patient profile?). Differences in patient and provider characteristics that influence choice of treatment can confound healthcare utilization and costs, especially when one of the treatments is used off label. One method to adjust for differences in patient profiles is propensity-score analysis.[24-26] Heckman et al argued convincingly that if patients are matched using the propensity score, up to 85% of the bias resulting from unequal distributions in patient characteristics can be removed.[27]

Propensity-score analysis can be implemented in a variety of ways. For medication and nonmedication cohorts we used a logistic regression model to predict the probability that patients belong in each group on the basis of their observed characteristics. The model covariates consisted of age, sex, region, and socioeconomic status variables, baseline healthcare comorbidities, utilization, and costs.

Once each patient was assigned a propensity score, patients in the medication cohort were matched with the pool of patients in the nonmedication cohort. Matching was undertaken using nearest neighbor 1:1 matching and the resulting matched cohort was compared to determine whether balanced cohorts were created.[28] Statistical analyses were performed using SAS v9.2 (SAS Institute, Cary, North Carolina) and STATA v10 (Stata Corp, College Station, Texas).

**Figure 1.** Patient Selection Process




For treatment types in the medication cohort, to further control for unobserved biases, the instrumental variable (IV) approach was used. One of the limitations of propensity-score matching analyses is that they control for observed bias (ie, selection from observed and measured factors) but not for unobserved bias. The IV approach is a technique that can be used to control for both observed and unobserved sources of bias, and to ascertain whether the results from the more standard approaches (propensity-score matching or multivariate regression) diverge from the IV results.

An instrument is a variable that does not belong in the explanatory equation and is correlated with the endogenous

**Table 1.** Baseline Characteristics of Opioid-Dependent Patients With and Without Any Medication

| Post-Index Period (6 months after index date) | Opioid-Dependence Treatment: Any Medication (N = 10,513) | Opioid-Dependence Treatment: No Medication (N = 8630) | |
|---|---|---|---|
| **Continuous variables** | **Mean (SD)** | **Mean (SD)** | ***P*** |
| Pre-index Deyo-Charlson comorbidity score | 0.35 (0.98) | 0.33 (0.95) | .1489 |
| Pre-index Elixhauser comorbid conditions | 1.56 (1.65) | 1.27 (1.61) | **<.0001** |
| Pre-index number of distinct psychiatric diagnoses | 2.56 (1.78) | 2.25 (1.85) | **<.0001** |
| Pre-index number of distinct psychiatric medications | 2.25 (2.04) | 1.61 (1.90) | **<.0001** |
| **Healthcare utilization** | | | |
| Pre-index number of detoxification facility days (number of days/1000 patients) | 1092 (3110) | 109 (1786) | **<.0001** |
| Pre-index inpatient (number of admissions/1000 patients) | | | |
| Detoxification and/or rehabilitation | 195 (462) | 16 (201) | **<.0001** |
| Opioid-related inpatient admission | 221 (523) | 48 (255) | **<.0001** |
| Non–opioid-related inpatient admission | 384 (884) | 277 (811) | **<.0001** |
| Pre-index outpatient (number of visits/1000 patients) | | | |
| Emergency department visits | 1410 (4241) | 1107 (3491) | **<.0001** |
| Opioid-related and physician provider | 266 (1795) | 105 (1080) | **<.0001** |
| Opioid-related and substance abuse psychosocial provider | 117 (1154) | 93 (1184) | .1471 |
| Non–opioid-related outpatient | 14,152 (16,098) | 12,951 (15,279) | **<.0001** |
| **Costs (per patient)** | | | |
| **Pre-index inpatient** | | | |
| Cost of detoxification and/or rehabilitation | $430 ($1497) | $0 ($0) | **<.0001** |
| Cost of opioid-related inpatient admission | $665 ($2768) | $156 ($1513) | **<.0001** |
| Cost of non–opioid-related inpatient admission | $4581 ($29,587) | $2689 ($16,097) | **<.0001** |
| **Pre-index outpatient** | | | |
| Cost of emergency department visits | $4450 ($1484) | $328 ($1326) | **<.0001** |
| Cost of opioid-related and physician provider | $28 ($292) | $9 ($202) | **<.0001** |
| Cost of opioid-related and substance abuse psychosocial provider | $14 ($175) | $6 ($116) | **.0002** |
| Cost of non–opioid-related | $30 ($42) | $26 ($35) | **<.0001** |
| **Pre-index pharmacy** | **Mean (SD)** | **Mean (SD)** | ***P*** |
| Cost of FDA-approved opioid-dependence medications | $2 ($53) | $0 ($0) | **<.0001** |
| Cost of other psychiatric medications | $176 ($531) | $77 ($366) | **<.0001** |
| Cost of nonpsychiatric medications | $913 ($2757) | $380 ($1865) | **<.0001** |
| **Total cost (including inpatient, outpatient, and pharmacy)** | **$10,710 ($34,138)** | **$6791 ($18,916)** | **<.0001** |

FDA indicates US Food and Drug Administration.

explanatory variables, conditional on the other covariates. In this study, because XR-NTX was not yet approved for the opioid dependence treatment indication (and was therefore being utilized off label), its use often required unique physician considerations and reimbursement processes resulting in unique cohort characteristics. Therefore, due to a high probability that unobserved bias would play a role in the use of this agent, copayment and physician/provider prescribing patterns derived from the claims and provider-level data served as instruments. The variables were tested to determine whether they were strong or weak instruments. From prior experience, it is known that physicians' prescribing patterns are very strong instruments because they are strongly related to treatment choices.

## Results

Table 1 reports the baseline demographic and clinical characteristics of the sample, stratified by the any medication and no medication groups. Patients were similar in terms of age (36.2 years vs 36.2, respectively; *P* = NS) and sex (61.5% male vs 60.3%, respectively; *P* = NS). Patients in the any medication cohort were less likely to be from the South

**Table 2.** Risk-Adjusted Outcomes in Opioid-Dependent Patients With and Without Any Medication

| Post-index period (6 months after index date) | Opioid-Dependence Treatment: Any Medication (N = 6658) | Opioid-Dependence Treatment: No Medication (N = 6658) | |
|---|---|---|---|
| **Outcome** | **Mean (SD)** | **Mean (SD)** | ***P*** |
| Post-index number of distinct psychiatric diagnoses | 3.01 (1.70) | 3.81 (2.14) | **<.0001** |
| Post-index number of distinct psychiatric medications | 2.49 (2.14) | 1.91 (2.05) | **<.0001** |
| **Healthcare utilization** | | | |
| Post-index number of detoxification facility days (number of days/1000 patients) | 447 (2250) | 4758 (7840) | **<.0001** |
| **Post-index inpatient (number of admissions/1000 patients)** | | | |
| Detoxification and/or rehabilitation | 74 (317) | 770 (721) | **<.0001** |
| Opioid-related inpatient admission | 111 (407) | 677 (811) | **<.0001** |
| Non–opioid-related inpatient admission | 292 (787) | 731 (1417) | **<.0001** |
| **Post-index outpatient (number of visits/1000 patients)** | | | |
| Emergency department visits | 1084 (3090) | 1041 (3125) | **.0372** |
| Opioid-related and physician provider | 1104 (3941) | 776 (3724) | **<.0001** |
| Opioid-related and substance abuse psychosocial provider | 301 (2054) | 553 (3196) | **<.0001** |
| Non–opioid-related outpatient | 17,389 (17,147) | 17,119 (17,663) | .1185 |
| **Costs (per patient)** | | | |
| **Post-index inpatient** | | | |
| Cost of detoxification and/or rehabilitation | $205 ($1240) | $2083 ($3434) | **<.0001** |
| Cost of opioid-related inpatient admission | $381 ($2299) | $1823 ($4800) | **<.0001** |
| Cost of non–opioid-related inpatient admission | $2928 ($15,420) | $4184 ($21,621) | **<.0001** |
| **Post-index outpatient** | | | |
| Cost of emergency department visit | $357 ($1211) | $288 ($1182) | **<.0001** |
| Cost of opioid-related and physician provider | $115 ($565) | $91 ($550) | **<.0001** |
| Cost of opioid-related substance abuse psychosocial provider | $25 ($213) | $47 ($361) | **<.0001** |
| Cost of non–opioid-related | $35 ($40) | $323 ($40) | **.0002** |
| **Post-index pharmacy** | | | |
| Cost of FDA-approved opioid-dependence medications | $1078 ($1256) | $1 ($41) | **<.0001** |
| Cost of other psychiatric medications | $278 ($755) | $132 ($498) | **<.0001** |
| Cost of nonpsychiatric medications | $851 ($2158) | $357 ($1169) | **<.0001** |
| **Total cost per patient (including inpatient, outpatient, and pharmacy)** | $10,192 ($19,472) | $14,353 ($25,780) | **<.0001** |

FDA indicates US Food and Drug Administration.

(18.5%) than patients in the no medication cohort (33.4%; *P* <.0001), and a smaller percentage had socioeconomic status scores in the bottom third (27.6%) relative to patients in the no medication cohort (39.8%; *P* <.0001).

As expected, given the possibilities for adverse selection, patients in the any medication cohort appeared to be sicker than those in the no medication cohort, both medically, with more having an Elixhauser comorbidity score of 3 or greater (22.9% vs 18.4%, respectively; *P* <.0001), and psychiatrically, with more having psychiatric diagnoses and taking psychiatric medications (*P* <.001 for all comparisons).

In terms of healthcare utilization, the 6 month pre-index utilization was higher in the any medication group, including number of detoxification facility days, detoxification and/or rehabilitation admissions, opioid-related and non–opioid-related inpatient and outpatient admissions, ED visits, and opioid-related provider visits.

This greater utilization in the any medication group translated into higher healthcare costs relative to the no medication group. Compared with patients not receiving medication, all of the inpatient and outpatient costs were significantly higher in those receiving medication. The

**Table 3.** Baseline Characteristics in Opioid-Dependent Patients by Pharmacotherapy

| Pre-Index Period | Opioid Dependence Medication | | | | | | |
|---|---|---|---|---|---|---|---|
| | XR-NTX (n = 156) | Oral NTX (n = 845) | | Buprenorphine (n = 7596) | | Methadone (n = 1916) | |
| **Patient characteristics** | **n (%)** | **n (%)** | ***P*** | **n (%)** | ***P*** | **n (%)** | ***P*** |
| Pre-index severity (Elixhauser ≥3) | 53 (34.0%) | 293 (34.7%) | .8658 | 1421 (18.1%) | **<.0001** | 635 (33.1%) | .8319 |
| **Continuous variables** | **Mean** | **Mean** | ***P*** | **Mean** | ***P*** | **Mean** | ***P*** |
| **Clinical characteristics** | | | | | | | |
| Pre-index Deyo-Charlson comorbidity score | 0.22 (0.67) | 0.24 (0.66) | .7494 | 0.26 (0.79) | .4480 | 0.77 (1.55) | **<.0001** |
| Pre-index Elixhauser comorbid conditions | 2.06 (1.75) | 2.05 (1.67) | .9304 | 1.37 (1.49) | **<.0001** | 2.05 (2.04) | .9105 |
| Pre-index number of distinct psychiatric diagnoses | 3.76 (2.06) | 3.78 (2.29) | .8825 | 2.48 (1.67) | **<.0001** | 2.23 (1.69) | **<.0001** |
| Pre-index number of distinct psychiatric medications | 2.70 (2.72) | 2.48 (2.27) | .3518 | 2.12 (1.90) | **.0086** | 2.62 (2.31) | .7277 |
| **Healthcare utilization** | | | | | | | |
| Pre-index number of detoxification facility days (number of days/1000 patients) | 2391 (5486) | 1782 (3474) | .1828 | 1188 (3201) | **.0071** | 301 (1918) | **<.0001** |
| **Pre-index inpatient (number of admissions/1000 patients)** | | | | | | | |
| Detoxification and/or rehabilitation | 353 (660) | 336 (568) | .7705 | 212 (475) | **.0091** | 53 (261) | **<.0001** |
| Opioid-related inpatient admission | 282 (1418) | 351 (583) | .5478 | 237 (509) | .6913 | 95 (368) | .1023 |
| Non–opioid-related inpatient admission | 718 (1135) | 680 (1077) | .7029 | 273 (717) | **<.0001** | 668 (1208) | .5999 |
| **Outpatient (number of visits/1000 patients)** | | | | | | | |
| Emergency department visits | 1154 (2717) | 1322 (3701) | .5055 | 1331 (3543) | .4240 | 1781 (6489) | **.0177** |
| Opioid-related and physician provider | 750 (3753) | 328 (1926) | .1718 | 284 (1844) | .1239 | 127 (1181) | **.0405** |
| Opioid-related and substance abuse psychosocial provider | 699 (3880) | 214 (1382) | .1250 | 113 (1109) | .0616 | 43 (576) | **.0366** |
| Non–opioid-related outpatient | 15,494 (14,515) | 14,669 (15,263) | .5184 | 12,125 (14,390) | **.0047** | 21,853 (20,137) | **<.0001** |
| **Costs (per patient)** | | | | | | | |
| **Pre-index inpatient** | | | | | | | |
| Cost of detoxification and/or rehabilitation | $1083 ($2793) | $767 ($1832) | .1754 | $458 ($1538) | **.0060** | $119 ($790) | **<.0001** |
| Cost of opioid-related inpatient admission | $607 ($1994) | $1108 ($3188) | **.0102** | $721 ($2946) | .4859 | $253 ($1598) | **.0320** |
| Cost of non–opioid-related inpatient admission | $3407 ($7753) | $4386 ($13,666) | .2096 | $2412 ($11,495) | .1189 | $13,360 ($64,017) | **<.0001** |
| **Pre-index outpatient** | | | | | | | |
| Cost of emergency department visits | $425 ($1316) | $455 ($1639) | .8049 | $445 ($1321) | .8502 | $467 ($1961) | .7180 |
| Cost of opioid-related and physician provider | $111 ($627) | $50 ($445) | .2449 | $29 ($292) | .1047 | $8 ($98) | **.0431** |
| Cost of opioid-related and substance abuse psychosocial provider | $74 ($567) | $41 ($311) | .4695 | $13 ($156) | .1762 | $4 ($53) | .1212 |
| Cost of non–opioid-related | $30 ($34) | $29 ($35) | .9012 | $26 ($37) | .1353 | $48 ($56) | **<.0001** |
| **Pre-index pharmacy** | | | | | | | |
| Cost of FDA-approved opioid -dependence medications | $157 ($408) | $0 ($0) | **<.0001** | $0 ($0) | **<.0001** | $0 ($0) | **<.0001** |
| Cost of other psychiatric medications | $282 ($722) | $217 ($600) | .2911 | $172 ($520) | .0604 | $164 ($521) | **.0473** |
| Cost of nonpsychiatric medications | $598 ($1285) | $530 ($1295) | .5459 | $845 ($2330) | **.0213** | $1377 ($4362) | **<.0001** |
| **Total cost (including inpatient, outpatient, and pharmacy)** | $10,393 ($12,677) | $11,527 ($17,455) | .3368 | $7,753,216 ($15,868,760) | **.0114** | $22,098 ($71,320) | **<.0001** |

FDA indicates US Food and Drug Administration; NTX, naltrexone; XR-NTX, extended-release injectable naltrexone.

6-month total cost including inpatient, outpatient, and pharmacy costs was $10,710 per patient in the any medication group compared with $6791 per patient in the no medication group.

Using propensity-score matching, 6658 patients from each group were matched. **Table 2** presents the risk-adjusted 6-month outcomes following the index treatment for patients in the any medication and no medication groups. Patients in the any medication group had fewer psychiatric diagnoses (3.01 vs 3.81), but more frequent use of distinct psychiatric medications (2.49 vs 1.91) relative to patients in the no medication group. Compared with patients in the no medication group, the number of detoxification facility days was significantly lower for patients in the any medication group (4758 vs 447 per 1000 patients). Post-index detoxification and/or rehabilitation admissions (74 vs 770) and opioid-related (111 vs 677) and non–opioid-related (292 vs 731) admissions were significantly lower per 1000 patients in the any medication group compared with the no medication group. Fewer inpatient admissions translated into lower inpatient costs in the any medication group. In particular, the 6-month costs per patient among those receiving medication for detoxification and/or rehabilitation admissions ($205 vs $2083) and opioid-related ($381 vs $1823) and non–opioid-related ($2928 vs $4184) admissions were significantly lower compared with those not receiving medication.

The pattern of healthcare utilization and cost for outpatient services was more mixed, with significantly higher use and cost associated with some categories of outpatient services in the any medication group. Overall healthcare cost savings, however, were $4161 per patient treated with medication relative to those not receiving medication ($10,192 vs $14,353).

Out of 10,513 patients who were given medication, 156 (1.5%) patients were treated with XR-NTX, 845 (8.3%) with oral NTX, 7596 (72%) with buprenorphine, and 1916 (18.2%) with methadone. Patients in the XR-NTX group were more likely to be male (75% vs 58.7%, 64.1%, and 51.4%, respectively; all $P$ <.01) and tended to reside in the eastern part of the United States relative to the other groups (37.8% vs 30.2%, $P$ = .06; 30.4%, $P$ <.05; and 14.2%, $P$ <.0001, respectively). They were older (36.9 years) compared with patients who received oral NTX (34.2; $P$ = .02) or buprenorphine (34.8; $P$ = .06), but younger relative to methadone users (42.3%; $P$ <.0001). The XR-NTX group had significantly fewer patients with the lowest socioeconomic score relative to all 3 oral medication groups (18.6% vs 31.7%, 26.0%, and 32.9%, respectively; all $P$ <.05).

Patient pre-index clinical characteristics in the 4 opioid medication groups are presented in **Table 3**. Although the distribution was similar among the other groups, patients given buprenorphine appeared to be healthier at the baseline, with significantly fewer patients with an Elixhauser index score of 3 or greater, and fewer distinct psychiatric diagnoses and medications.

Patients in the XR-NTX cohort spent significantly more days in a detoxification facility (2391 per 1000 patients) relative to those in the buprenorphine (1188) and methadone (301) cohorts. Similarly, the number of patients admitted to detoxification and/or rehabilitation centers at baseline was greater for those given XR-NTX (353) versus those given buprenorphine (212) and methadone (53). This translated into a higher cost for detoxification and rehabilitation at baseline in patients receiving XR-NTX. Outpatient resource use and cost were similar among the groups at baseline, excepting significantly greater opioid-related outpatient physician visits and costs and significantly less non–opioid-related outpatient visits and costs in the XR-NTX group compared with the methadone group.

Total healthcare cost during the 6-month pre-index period for patients in the XR-NTX group was significantly higher versus the buprenorphine group, but lower versus the methadone group. Among opioid-dependent patients at baseline, there were no significant differences in costs between the XR-NTX and oral NTX groups.

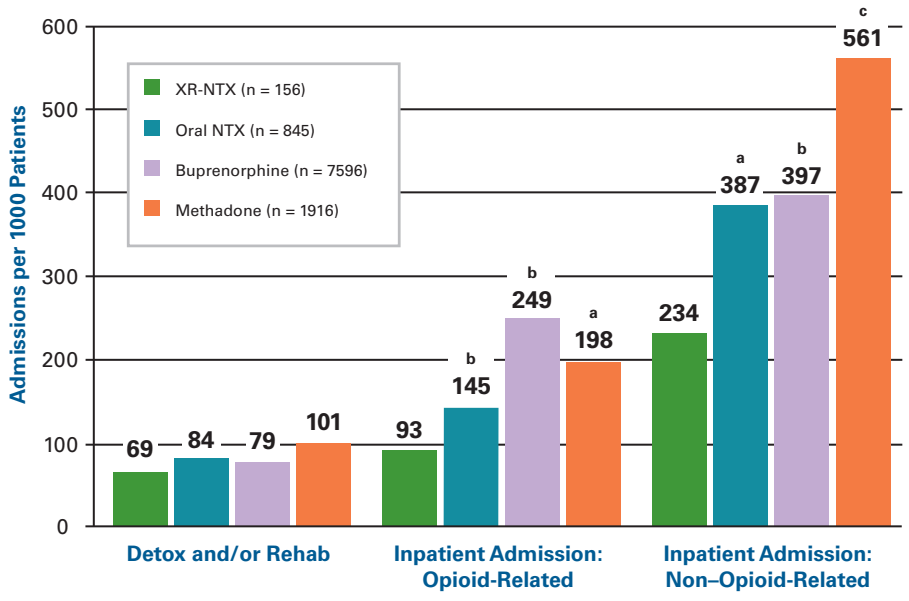
Overall, the XR-NTX group showed notable cohort differences, including a greater percentage of patients who were male, were from the eastern United States, had higher socioeconomic status, and had higher utilization rates for physician services and detoxification. This pattern indicated a substantial degree of prescribing bias, consistent with the fact that XR-NTX was not yet approved by the FDA for the prevention of relapse to opioid dependence following detoxification. Baseline differences among the opioid treatment groups were controlled using the instrumental variable approach; risk-adjusted outcomes are presented in **Figure 2** and **Table 4**.

Compared with patients given oral NTX, those given XR-NTX had a greater number of refill persistence days (55 vs 61 days, respectively), fewer distinct psychiatric medications (2.34 vs 1.99, respectively), fewer detoxification days (71 vs 62 per 1000 patients, respectively), fewer detoxification or rehabilitation admissions (84 vs 69, respectively), fewer ED visits (767 vs 608, respectively), and significantly fewer opioid-related inpatient admission rates (145 vs 93, respectively) and non–opioid-related inpatient admission rates (387 vs 234, respectively) (Figure 2A).

The overall healthcare costs for patients given XR-NTX were not different from those given buprenorphine,

**Figure 2.** Opioid-Dependence Pharmacotherapies: Health Economic Outcomes 6 Months After Index Date

**A.** Inpatient Admissions per 1000 Patients:
Instrumental Variable Matched Outcomes 6 Months After Index Date




**B.** Inpatient Costs per Patient:
Instrumental Variable Matched Outcomes 6 Months After Index Date

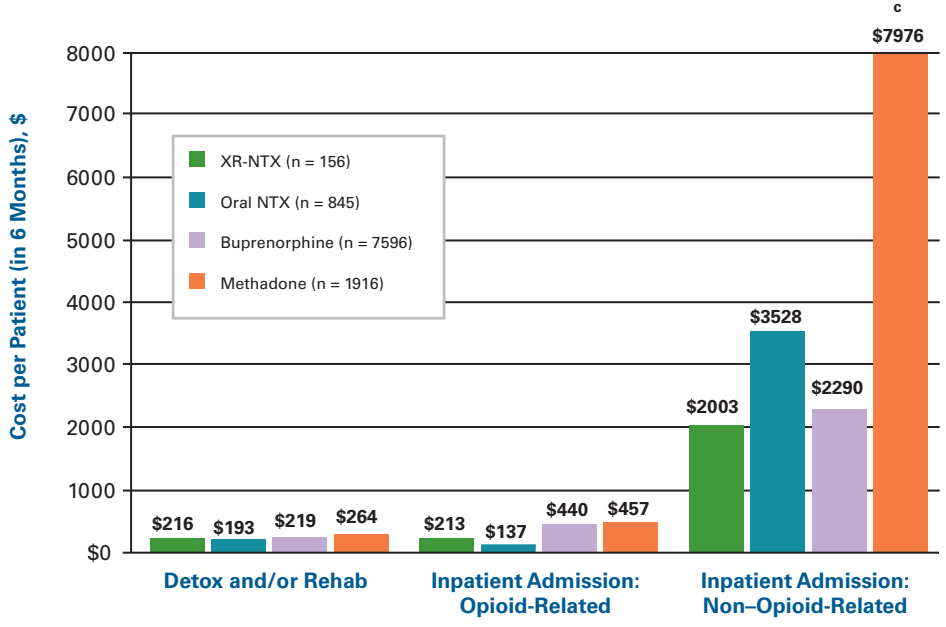
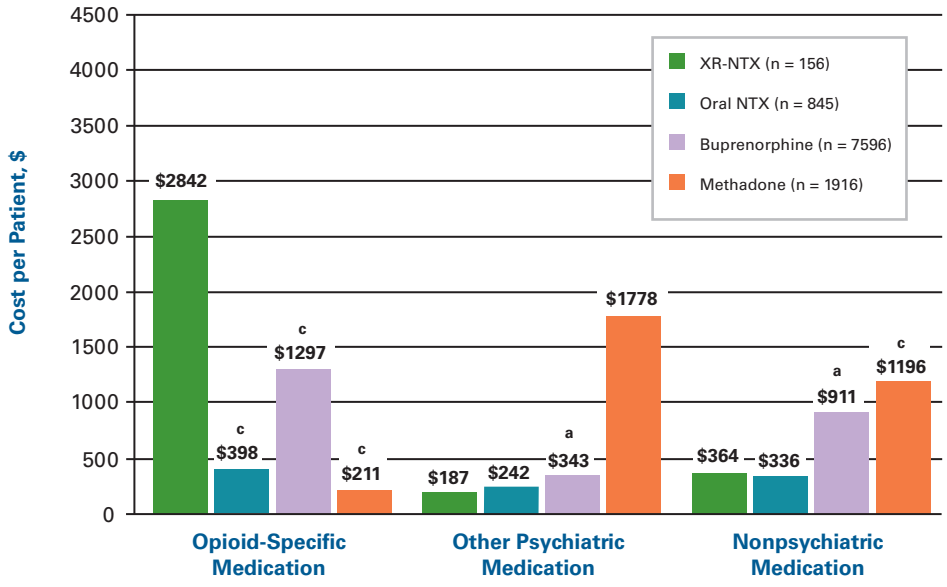
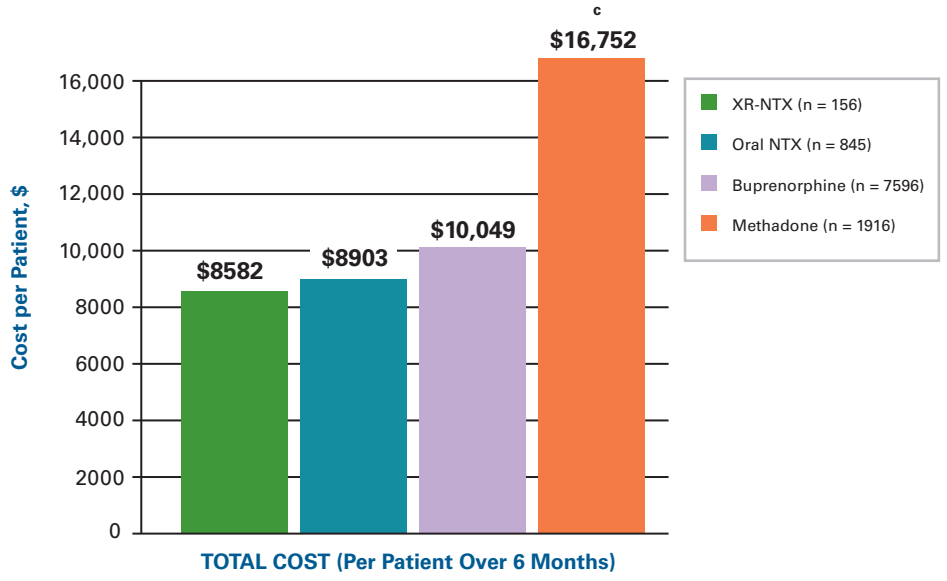


**Figure 2.** Opioid-Dependence Pharmacotherapies: Health Economic Outcomes 6 Months After Index Date *(Continued)*

**C.** Pharmacy Costs per Patient:
Instrumental Variable Matched Outcomes 6 Months After Index Date




**D.** Total Cost per Patient (inpatient + outpatient + pharmacy costs):
Instrumental Variable Matched Outcomes 6 Months After Index Date




NTX indicates naltrexone; XR-NTX, extended-release injectable naltrexone.
*P* vs XR-NTX:
[a] *P* <.05.
[b] *P* <.01.
[c] *P* <.001.

**Table 4.** Risk-Adjusted Outcomes Measures in Opioid-Dependent Patients by Pharmacotherapy

| Post-Index Period | Opioid Dependence Medication | | | | | | |
|---|---|---|---|---|---|---|---|
| | XR-NTX (n = 156) | Oral NTX (n = 845) | | Buprenorphine (n = 7596) | | Methadone (n = 1916) | |
| **Compliance and persistence with therapy** | % | % | *P* | % | *P* | % | *P* |
| Continuous MPR ≥0.8 | 21 | 8 | **<.0001** | 34 | **.0105** | 29 | .0959 |
| **Outcome** | Mean | Mean | *P* | Mean | *P* | Mean | *P* |
| Persistence days with index medication | 61.49 | 54.98 | .229 | 68.92 | 0.142 | 62.8 | .798 |
| Post-index number of distinct psychiatric diagnoses | 3.52 | 3.47 | .727 | 3.12 | **.004** | 2.7 | **<.0001** |
| Post-index number of distinct psychiatric medications | 1.99 | 2.34 | .062 | 2.59 | **.001** | 2.72 | **<.0001** |
| **Healthcare utilization** | | | | | | | |
| Post-index number of detoxification facility visits (number of visits/1000 patients) | 62 | 71 | .672 | 66 | .851 | 82 | .333 |
| **Post-index inpatient (number of admissions/1000 patients)** | | | | | | | |
| Detoxification and/or rehabilitation | 69 | 84 | .61 | 79 | .704 | 101 | .243 |
| Opioid-related inpatient admission | 93 | 145 | **.005** | 249 | **.007** | 198 | **.025** |
| Non–opioid-related inpatient admission | 234 | 387 | **.027** | 397 | **.001** | 561 | **<.0001** |
| **Post-index outpatient (number of visits/1000 patients)** | | | | | | | |
| Emergency department visits | 608 | 767 | .575 | 1092 | .067 | 1590 | **<.0001** |
| Opioid-related and physician provider | 869 | 395 | .173 | 1362 | .13 | 452 | .208 |
| Opioid-related and substance abuse psychosocial provider | 528 | 452 | .705 | 391 | .465 | 241 | .132 |
| Non–opioid-related outpatient | 16,654 | 16,338 | .824 | 16,840 | .889 | 22,054 | **<.0001** |
| **Costs (per patient)** | | | | | | | |
| **Post-index inpatient** | | | | | | | |
| Cost of detoxification and/or rehabilitation | $216 | $193 | .571 | $219 | .721 | $264 | .619 |
| Cost of opioid-related inpatient admission | $213 | $137 | .725 | $440 | .263 | $457 | .235 |
| Cost of non–opioid-related inpatient admission | $2003 | $3528 | .296 | $2290 | .834 | $7976 | **<.0001** |
| **Post-index outpatient** | | | | | | | |
| Cost of emergency department visits | $184 | $283 | .409 | $402 | .051 | $462 | **.014** |
| Cost of opioid-related and physician provider | $95 | $6 | .077 | $150 | .243 | $52 | .37 |
| Cost of opioid-related and substance abuse psychosocial provider | $29 | $267 | .903 | $34 | .782 | $22 | .735 |
| Cost of non–opioid-related | $4510 | $4068 | .248 | $3678 | **.025** | $6173 | **.0005** |
| **Post-index pharmacy** | | | | | | | |
| Cost of FDA-approved opioid-dependence medications | $2842 | $398 | **<.0001** | $1297 | **<.0001** | $211 | **<.0001** |
| Cost of other psychiatric medications | $187 | $242 | .431 | $343 | **.017** | $1778 | .888 |
| Cost of nonpsychiatric medications | $364 | $336 | .904 | $911 | **.014** | $1196 | **<.0001** |
| **Total cost (per patient = inpatient, outpatient, and pharmacy)** | $8582 | $8903 | .867 | $10,049 | .414 | $16,752 | **<.0001** |

FDA indicates US Food and Drug Administration; MPR, medication possession ratio; NTX, naltrexone; XR-NTX, extended-release injectable naltrexone.

despite significantly greater costs for the FDA-approved opioid-dependence medication ($2842 vs $1297, respectively)(Figure 2C). Patients receiving buprenorphine had greater refill persistence than those receiving XR-NTX (69 vs 61 days, respectively), but had significantly more opioid-related inpatient admissions (249 vs 93 per 1000 patients, respectively) (Figure 2A), more non–opioid-related inpatient admissions (397 vs 234, respectively) (Figure 2A), and more ED visits (1092 vs 608, respectively).

Given these overall utilization differences and their related costs, the overall healthcare costs per patient in the group treated with methadone were significantly greater than those with XR-NTX ($16,752 vs $8582, respectively) (Figure 2D), despite the significantly lower cost for the opioid dependence pharmacotherapy ($211 vs $2842, respectively) (Figure 2C). Patients given methadone or XR-NTX showed similar prescription persistence. Compared with patients given XR-NTX, those given methadone had a significantly greater number of distinct psychiatric diagnoses, but lower use of distinct psychiatric medications. Also, patients receiving methadone spent more days in detoxification (82 vs 62 per 1000 patients, respectively), had more detoxification or rehabilitation admissions (101 vs 69, respectively) (Figure 2A), had more opioid-related inpatient admissions (198 vs 93, respectively) (Figure 2A), had significantly more ED visits (1590 vs 608, respectively), and had significantly more non–opioid-related outpatient visits (22,054 vs 16,654, respectively) compared with those receiving XR-NTX.

## Discussion

The combined data from these 2 large insurance data sets made possible the first study to date examining healthcare costs and utilization for the full set of currently available opioid-dependence treatments. This risk-adjusted analysis compared outcomes in 13,316 patients who received any versus no medication for opioid-dependence disorder and 10,513 patients who received 1 of the 4 FDA-approved pharmacologic therapies. Thus, this study was one of the largest health economic studies in this disorder to date, and the first such study to analyze treatment with XR-NTX. The study was a comprehensive analysis of total healthcare costs paid and corresponding healthcare service utilization. Compared with opioid-dependence treatment that did not include medication, medication-assisted treatment was associated with significantly fewer admissions for detoxification and/or rehabilitation, opioid-related inpatient medical care, and non–opioid-related inpatient medical care. In all of these inpatient service categories, costs were significantly lower in patients who received a medication, and total healthcare costs, including inpatient, outpatient, and pharmacy costs, were 29% lower for patients who received a medication for their opioid dependence, despite significantly higher costs for medications. Patients given XR-NTX had significantly fewer opioid-related and non–opioid-related hospitalizations than those given any of the 3 oral agents, fewer ED visits than patients who received methadone, and an overall pattern of the lowest use in all categories of inpatient utilization (Figure 2A). Despite significantly higher costs for XR-NTX, total healthcare costs, including inpatient, outpatient, and pharmacy costs, were not significantly greater than total costs with oral NTX or buprenorphine, and were 49% lower than with methadone (Figure 2D).

This retrospective claims analysis lacked clinical variables such as drug use, severity, and overdose; however, the rate of hospital admissions is an intensive utilization variable that may also represent a proxy for morbidity, which has importance in addition to cost implications. In this study, medication was associated with 29% lower costs than nonpharmacologic treatment, whereas the relative risk reduction associated with medication was 84% for opioid-related hospitalization and 60% for non–opioid-related admission. Of the 4 FDA-approved medications, the total cost associated with XR-NTX was not significantly different from oral NTX and buprenorphine, and it was 49% lower than that with methadone. However, Figure 2A shows that the risk of an opioid-related hospitalization in patients given XR-NTX was 36% lower than that with oral NTX, 63% less than with buprenorphine, and 53% less than with methadone; the risk for non–opioid-related hospitalization with XR-NTX was 40%, 41%, and 58% lower than that with oral NTX, buprenorphine, and methadone, respectively. Similar results have been reported in the treatment of alcohol dependence, with 3 large retrospective claims analyses showing that medication-assisted treatment was associated with lower total healthcare costs than nonmedication treatment.[29-31] Also, XR-NTX treatment cohorts demonstrated utilization and/or cost benefits in relation to approved oral agents for alcohol dependence.

These overall healthcare cost results highlight the problem of healthcare budget segmentation. The any medication group had total medication costs that were several times greater than those with no anti-opioid medications; however, overall healthcare costs were 29% less in those receiving opioid-dependence medication. Likewise, the cost of XR-NTX itself was more than 10-fold that of methadone, but total healthcare costs associated with methadone were nearly double those of XR-NTX. While many other factors must be taken into account, these findings suggest that stand-alone budgeting based on pharmacy costs may be counterproduc-

tive in addiction treatment—the cost offsets of a "carve out" arrangement may not accrue to medical cost centers.

Refill persistence and outcomes showed an inverse relationship among once-monthly XR-NTX and daily oral NTX. Once XR-NTX is administered by a healthcare professional, the active ingredient, NTX, is present for a month and cannot be removed from the system. Daily oral NTX, however, was found to be ineffective due to poor treatment adherence.[32] In the present study, 21% of patients receiving XR-NTX possessed the injection at least 80% of the study days, a percentage which was 2.6 times that with oral NTX (8%). The XR-NTX group had significantly fewer opioid-related and non–opioid-related hospitalizations. Compared with patients given XR-NTX, those given methadone or buprenorphine had similar refill persistence, and a greater percentage of these patients possessed their medication for at least 80% of the duration. This may reflect patient satisfaction, treatment effectiveness, and/or the fact that both agents have agonist properties that maintain opioid physical dependence and result in symptoms of withdrawal upon cessation.

Limitations of retrospective claims analyses include the absence of randomized controls. Therefore, treatment assignment resulted in imbalances in important clinical variables. There were substantial differences between the cohorts at baseline, some of which may have been unobserved (eg, differential patient motivation or provider characteristics). Possible reasons for these differences include regional differences in access to methadone and buprenorphine, differential reimbursement, and provider and community attitudes toward opioid-maintenance therapy and patient self-selection (eg, orientation toward an opioid-free recovery). These differences were particularly salient because at the time of data collection, XR-NTX was not yet approved by the FDA for opioid-dependence treatment, resulting in a notably smaller cohort receiving this medication. Patients who were seeking XR-NTX and prescribers offering it were possibly quite different from patients and providers utilizing other agents. The statistical methods we used, while designed to adjust for observed and unobserved differences and bias, may have been imperfect in this respect, and thus the observed findings may reflect unadjusted confounding.

Another limitation was that group sizes varied considerably in this study and, in general, studies of the relationship between rare exposures to a risk factor require large sample sizes to obtain reasonable estimates. The sample size for the XR-NTX group in particular was smaller than the other groups, raising questions about generalizability and the interpretation of statistical tests. However, the overall sample size was large, and the findings of the highest cost incidents for the XR-NTX comparisons show relatively good internal consistency, supporting the validity of the findings for this XR-NTX sample. Further research, however, should be conducted with larger samples for confirmation, now that XR-NTX is FDA-approved for opioid dependence. The index date for the any medication group permitted inclusion of a period of psychosocial treatment prior to medication-assisted treatment (in contrast to the no medication group), possibly leading to underestimated costs for the treatment episode in the medication group. We excluded patients who transitioned from one medication to another. It is not known what percentage of patients given oral NTX were subject to mandated or monitored administration (ie, to retain a professional license), what percentage of patients given buprenorphine intended to undergo detoxification only, or what percentage of patients given methadone were treated in a licensed methadone maintenance clinic versus receiving methadone for the treatment of pain outside of an opioid treatment program. Claims data do not record duration of opioid dependence or assessments of ongoing illicit drug use. No information was available regarding recommended or adequate durations of treatment, and daily treatment adherence could not be inferred by prescription refills. Medications have adverse effects, some of which are noted in boxed warnings in the prescribing information, and adverse effects differ between the oral and injectable agents; adverse events data were not examined. The 6-month study period did not provide long-term outcome data, and the patient population had some distinct characteristics, including having commercial insurance for a full year.

The study had some relevant strengths, despite these limitations. To establish comparability between cohorts, propensity-score matching was used for the any versus no medication comparison, and instrumental variable analysis was added to the 4-way medication comparison to control for both observed and unobserved bias. Refill possession duration was relatively brief, but this duration was real, and treatment effects were therefore examined during and beyond the average medication treatment duration. A good degree of internal consistency was apparent in the patterns of higher utilization of intensive services for the comparisons of no medication versus any medication and the 3 oral agents versus XR-NTX. Patients in this study were commercially insured and XR-NTX had yet to receive FDA approval for the treatment of opioid dependence; nevertheless, from the perspective of commercial insurance, these results would be expected to have external validity, given the large sample sizes for the no medication and oral medication cohorts, which consisted of real-world patients treated by community providers in standard treatment settings. Opioid agonist treatment in the

United States has traditionally been government funded, but 33.1% to 61.6% of public programs now report commercial insurance funding[33] and increasing commercial coverage is part of the National Drug Control Strategy.[3]

The vast majority (98.5%) of 270,881 patients enrolled in US opioid treatment programs are receiving methadone.[33] In the United States, the annual cost for counseling plus methadone services is at least $4700, whereas the combined mean costs of methadone plus opioid-related physician and psychosocial services in this study over 6 months was much less, suggesting that these data may underestimate the difference between XR-NTX and methadone costs.[1,34] Furthermore, this study raises a question about the medical care of patients receiving methadone. These data show a low use of physician providers and a very high use of ED services in patients given methadone, raising a quality-of-care issue that is worthy of further exploration.

This study's cost evaluation was limited to direct healthcare expenditures, but a review of 11 studies found that the largest source of cost benefit associated with substance abuse treatment was reduction in criminal activity, followed by improved earning potential; the contribution from healthcare was third.[35] Future studies should include these cost areas.

Regulatory, licensing, and financing policies have separated treatment of opioid addiction from medical care, significantly limiting access to care and further stigmatizing both individuals with these addictions and pharmacotherapy itself. For many years, it has been easier for individuals to acquire drugs than to receive treatment for addiction. The integration of opioid-dependence treatment into mainstream medicine is a key component of the White House's national drug strategy, but the barriers are numerous—training deficits, organizational obstacles, negative attitudes toward addictions, and fears about additional costs.[3] While methadone is limited to specially licensed programs, the other agents can be delivered in any clinical setting (eg, office-based physician practices and community health centers). Based on pretreatment comorbidity and utilization, patients in this study who received medication tended to be sicker at baseline. This supports the need for physician involvement in the care of patients with addiction. With medical treatment, total costs and use of inpatient services of all types were lower, supporting the potential cost benefit of increased integration of addiction and primary care services. This has been previously demonstrated in patients with substance abuse–related medical conditions.[36]

The majority of patients with opioid-dependence disorder in the United States remain untreated. Yet, the literature on cost-benefit studies with opioid agonist maintenance therapy consistently finds that benefits exceed costs, even when not all benefits are accounted for in the analysis.[37,38] The National Institute on Drug Abuse guide states that no single treatment is appropriate for all patients, that treatment needs to be readily available, and that medications are an important treatment element, in combination with behavioral approaches.[1] Further research is needed, with larger XR-NTX populations, for longer durations, and preferably with prospective designs or cohort-matching methods analogous to what were utilized in the present study. The current findings regarding opioid-dependence pharmacotherapy are compelling, and the cost findings regarding XR-NTX deserve further exploration in larger cohorts and trials using experimental designs that collect treatment outcome and cost data.

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***Authorship information:*** Concept and design (MC, DRG); acquisition of data (OB); analysis and interpretation of data (OB, MC, DAF, DRG); drafting of the manuscript (OB, MC, DAF, DRG); critical revision of the manuscript for important intellectual content (MC, DAF, DRG); statistical analysis (OB); obtaining funding (DRG); and administrative, technical, or logistic support (DRG).

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# Public Policy Directory

This document provides contact information for organizational leaders who, to our knowledge, are utilizing VIVITROL® (naltrexone for extended-release injectable suspension). This is not intended to provide any claims of product safety or efficacy. All programs and individuals noted below are fully independent of Alkermes financial or in-kind support, unless otherwise noted. Some initiatives are listed in more than one section of this Directory.

Treatment with VIVITROL should be part of a comprehensive management program that includes psychosocial support. Opioid-dependent patients, including those being treated for alcohol dependence, must be opioid-free at the time of initial VIVITROL administration. VIVITROL is indicated for the treatment of alcohol dependence in patients who are able to abstain from alcohol in an outpatient setting prior to initiation of treatment with VIVITROL. Patients should not be actively drinking at the time of initial VIVITROL administration. VIVITROL is also indicated for the prevention of relapse to opioid dependence, following opioid detoxification.

## State Initiatives

| Name | Affiliation | Position | State | Email | Phone | Descriptions |
|---|---|---|---|---|---|---|
| Bonnie Campbell, LCSW | Baltimore Substance Abuse Systems | Director of Policy and Planning | MD | bcampbell@bsasinc.org | (410) 637-1900 Ext. 252 | VIVITROL initiated at both inpatient and outpatient locations for Alcohol Dependence. |
| Lucy Garrighan Short | JADE Wellness Center | CEO | PA | lucy@myjadewellness.com | (412) 400-5555 | Pennsylvania State Medicaid pilot for opioid dependence. The behavioral health plan is partnering with the managed medicaid plans. |
| Mark Stringer, M.A. | Missouri Department of Mental Health, Division of Alcohol and Drug Abuse | Director | MO | Mark.Stringer@dmh.mo.gov | (573) 751-4942 | Statewide implementation of VIVITROL paid for by the state for those under probation and parole supervision and for the uninsured. Program initiated in 2008. |
| Ximena Johnson | Florida Department of Children and Families, Substance Abuse Program Office | Performance Improvement Coordinator | FL | ximena_johnson@dcf.state.fl.us | (850) 717-4437 | VIVITROL offered in multiple centers in FL for high-risk, uninsured high-need patients. Expanded to criminal justice and veterans populations with recently-awarded ATR grant. Program initiated in |
| Stephanie Wick, MS | Department of Social and Rehabilitation Services, Addiction and Prevention | Director | KS | stephanie.wick@srs.ks.gov | (785) 296-6807 | High risk/high need patients through a collaboration between Kansas SSA and Value Options, and Regional Assessment Center. |
| Suzanne Borys | NJ Division of Mental Health and Addiction Services | Asst. Director, Research, Planning & Policy | NJ | Suzanne.borys@dhs.state.NJ.us | (609) 984-4050 | VIVITROL for DUI offenders including those with opioid dependence. |
| Wendy McCullough | Stairways Forensics Clinic | Director | PA | wmccullough@stairwaysbh.org | (814) 878-3472 | Pennsylvania State Medicaid pilot for opioid dependence. The behavioral health plan is partnering with the managed medicaid plans. |

## City & County-based Initiatives

| Name | Affiliation | Position | State | Email | Phone | Descriptions |
|---|---|---|---|---|---|---|
| Angela Johnsen, MSW | Warren County, OH, Mental Health Recovery Centers | Outpatient Director | OH | ajohnsen@mhrswcc.org | (513) 228-7877 | VIVITROL provided to reentering offenders leaving the county detention center, with the first injection planned prior to release. Continuing care with VIVITROL to occur in the community. |
| Beth Jones, MS,LCAC | Harford County Department, Division of Addiction Services | Director | MD | bethjones@dhmh.state.md.us | (410 )877-2360 | VIVITROL for high risk/high need patients. |
| Bonnie Campbell, LCSW | Baltimore Substance Abuse Systems | Director of Policy and Planning | MD | bcampbell@bsasinc.org | (410) 637-1900 Ext. 252 | VIVITROL initiated at both inpatient and outpatient locations for Alcohol Dependence. |
| Catherine McAlpine | Montgomery County | Director | MD | Catherine.McAlpine@montgomerycountymd.gov | (240) 777-4710 | VIVITROL provided for high-risk/high need patients, including drug courts participants. |
| Dr. Debra O'Beirne | Fairfax County, VA Engagement Program | Addiction Medicine Psychiatrist | VA | debra.O'Beirne@fairfaxcounty.gov | (703) 517-3620 | Vivitrol used as a tool to support recovery process in high-risk patients. |
| Holly McCravey | Los Angeles County Department of Public Health, Substance Abuse Prevention | Acting Program Administrator for Adult Treatment and | CA | hmccravey@ph.lacounty.gov | (626) 299-4197 | VIVITROL and case management for repeat detox population. Also, Vivitrol in 12 drug courts and planning jail re-entry initiatives. |
| Jana Kyle | Fayette County Drug and Alcohol Bureau | Director | PA | jkyle@fcdac.org | (724) 438-3576 | VIVITROL for high risk/high need patients. |
| Judi Rosser | Blair County Drug and Alcohol Bureau | Director | PA | jrosser@blairdap.org | (814) 693-9663 | VIVITROL for offenders in Drug Court. |
| Linda Gallagher | Hamilton County Mental Health and Recovery Services Board | Vice President AOD Services | OH | lindag@hamilton.mhrsb.state.oh.us | (513) 946-8690 | Vivitrol provided to opioid dependent drug court participants. Funded by SAMHSA drug court expansion grant. |
| Lisa Roberts, RN | Portsmouth Public Health Department | Public Health Nurse | OH | Lisa.Roberts@odh.ohio.gov | (740) 353-2418 Ext. 293 | VIVITROL provided to uninsured alcohol and opioid dependent patients. |
| Randy Spangle | Ashland County, Division of Mental Health and Substance Abuse Services | Director | WI | aac@ncis.net | (715) 682-5207 | VIVITROL provided for repeat DWI offenders. |
| Rebecca Hogamier, MBA, LCADC | Washington County, Division of Addiction and Mental Health Services | Director | MD | rhogamier@dhmh.state.md.us | (240) 313-3283 | VIVITROL provided to reentering offenders leaving the county detention center, with the first injection planned prior to release. Continuing care with VIVITROL to occur in the community. Note: This |
| Richard Wynn | Franklin/Fulton Drug and Alcohol Bureau | Human Services Director | PA | rcwynn@franklincountypa.gov | (717) 263-1256 | VIVITROL for high risk/high need patients. |
| Sue Doyle, RN | Carroll County | Director | MD | sdoyle@dhmh.state.md.us | (410) 876-4410 | VIVITROL provided for high-risk/high need patients in both residential and outpatient settings and also for Drug Court clients. |
| Sue Gadacz, MA | Milwaukee County Behavioral Health | Director | WI | Susan.Gadacz@milwcnty.com | (414)257-7023 | VIVITROL for clients in Milwaukee County Drug Courts; add'l initiative with repeat detox pts. |
| Tamara C. Feest | Oneida County OWI Court | OWI Court Administrator | WI | TF@thehumanservicecenter.org | (715) 369-2215 | VIVITROL for 3rd time OWI offenders. |

## Criminal Justice Settings

| Name | Affiliation | Position | State | Email | Phone | Descriptions |
|---|---|---|---|---|---|---|
| Carol Carlson | Milwaukee Drug Court | Court Coordinator | WI | ccarlson@JusticePoint.org | (414) 223-1341 | Vivitrol for Drug Court Offenders. |
| Christine Costa | Barnstable Community Corrections Center | Program Manager | MA | cti24@[redacted] | (774) 470-1375 | VIVITROL and treatment provided to probationers/parolees as part of the Office of Community Corrections treatment plan. |
| Gregg Dockins | Gateway Foundation | Director, Corrections Initiatives | MO | gdockins@gatewayfoundation.org | (815) 220-9058 | Vivitrol for probation and parole clients. |
| H. Bruce Hayden, LMHC, CAP | Banyan Health Systems | President & CEO | FL | bhayden@spectrumprograms.org | (305) 757-0602 | Program provides treatment with VIVITROL through the Florida Indigent Drug Program. |
| Hartwell Dowling, LCSW | Maine Administrative Office of the Courts | Specialty Court Manager and Grant Coordinator | ME | Hartwell.Dowling@courts.maine.gov. | (207) 287-4021 | Part of NEADCP Project. VIVITROL for opioid or alcohol drug court participants. |
| Holly McCravey | Los Angeles County Department of Public Health, Substance Abuse Prevention | Acting Program Administrator for Adult Treatment and | CA | hmccravey@ph.lacounty.gov | (626) 299-4197 | VIVITROL and case management for repeat detox population. Also, Vivitrol in 12 drug courts and planning a jail re-entry initiative. |
| Hon. Alan Blankenship | Stone County Drug Court | Judge | MO | alan.blankenship@courts.mo.gov | (417) 357-3085 | VIVITROL for Drug Court Offenders. |
| Hon. Carl Ashley | Milwaukee Drug Court | Judge | WI | carl.ashley@wicourts.gov | (414) 278-5316 | VIVITROL for Drug Court Offenders. |
| Hon. Dawnn Gruenburg | Warren Felony Drug Court | Judge | MI | dgruenburg@cityofwarren.org | (585) 574-4974 | VIVITROL for Drug Court Offenders; Judge Gruenburg's court participated in an evaluation of VIVITROL in Drug Courts. |
| Hon. Fred Moses | Hocking County Municipal Court | Judge | OH | fmoses@co.hocking.oh.us | (614) 404-8040 | Vivitrol provided to opioid dependent drug court participants. |
| Hon. Glen Yamahiro | Milwaukee Drug Court | Judge | Wi | glen.yamahiro@wicourts.gov | (414) 278-5316 | Vivitrol for Drug Court Offenders. |
| Hon. Harry L. Powazeck | California State Court, Superior Courts, San Diego County | Judge | CA | Call Judge Powazek | (760) 201-8113 | Vivitrol for drug court offenders. |
| Hon. Harvey Hoffman | Eaton County DWI Court | Judge | MI | HHoffman@eatoncounty.org | (517) 543-7500 Ext. 4030 | VIVITROL for DWI Court Offenders; Judge Hoffman's court participated in an evaluation of VIVITROL in Drug Courts. |
| Hon. James Kandrevas | Southgate Drug Court | Judge | MI | kgray@28dc.com | (734) 258-3068 | VIVITROL for Drug Court Offenders; Judge Kandrevas' court participated in an evaluation of VIVITROL in Drug Courts. |
| Hon. James Sullivan | St Louis Drug Court | Commissioner and Judge | MO | james.sullivan@courts.mo.gov | (314) 641-8212 | VIVITROL for Drug Court Offenders; Judge Sullivan's court participated in an evaluation of VIVITROL in Drug Courts. |
| Hon. John Marksen | Dane County OWI Court | Judge | WI | john.markson@wicourts.gov | (608) 266-4231 | VIVITROL for 3rd time OWI offenders. |
| Hon. Michael Noble | St Louis Drug Court | Commissioner/Judge | MO | mnoble1@courts.mo.gov | (314) 552-2030 | VIVITROL for DWI Court Offenders; Judge Noble's court participated in an evaluation of VIVITROL in Drug Courts. |
| Hon. Oscar Hale | Webb County Drug Court | Judge | TX | 406@webbcountytx.gov | (956) 523-5954 | Vivitrol for Drug Court Offenders. |
| Hon. Peggy Davis | Green County DWI Court | Commissioner and Judge | MO | Peggy.davis@courts.mo.gov | (417) 829-6620 | VIVITROL for DWI Court Offenders; Judge Davis' court participated in an evaluation of VIVITROL in Drug Courts. |
| Hon. Phil Britt | Stoddard County Drug Court | Judge | MO | phillip.britt@courts.mo.gov | (573) 888-7091 | VIVITROL for DWI Offenders. |
| Hon. Phillip Ohlms | St Charles DWI Court | Commissioner and Judge | MO | Phil.Ohlms@Courts.Mo.gov | (636) 949-7462 | VIVITROL for DWI Court Offenders. |

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|---|---|---|---|---|---|---|
| James Gibbs | Southgate Drug Court | Chief Probation Officer | MI | jgibbs@28thdistrictcourt.com | (734) 258-3068 Ext. 3643 | VIVITROL for Drug Court Offenders; Mr. Gibbs' court participated in an evaluation of VIVITROL in Drug Courts. |
| Jesse Hernandez | Webb County Drug Court | Director of Treatment | TX | lafamilia@[redacted] | (956) 795-0948 | Vivitrol for Drug Court Offenders. |
| John Hamilton, LMFT | Recovery Network of Programs, Inc. | CEO | CT | John.Hamilton@rnpinc.org | (203) 929-1954 | New England Regional Drug Court (NEADCP) project involving VIVITROL for drug court participants. Medication funded through State Medicaid. |
| Linda Gallagher | Hamilton County Mental Health and Recovery Services Board | Vice President AOD Services | OH | lindag@hamilton.mhrsb.state.oh.us | (513) 946-8690 | Vivitrol provided to opioid dependent drug court participants. Funded by SAMHSA drug court expansion grant. |
| Lt. Kristen Shea | Hampshire Sheriff's Department | Project Leader | MA | Kristen.shea@hsd.state.ma.us | (413) 584-5911 Ext:254 | VIVITROL and treatment provided to reentering offenders prior to leaving the county correctional facility and to continue into the community. |
| Mark Stanford, Ph.D. | Addiction Medicine and Therapy Division, Dept. of Alcohol and Drug Services, Santa Clara Co. | Director, Medication Assisted Treatment | CA | mark.stanford@hhs.sccgov.org | (408) 885-4078 | Vivitrol initiated in jail and continued in the community alcohol and drug programs. |
| Marta Nolan, PhD. | Missouri Department of Corrections | Asst Director, Substance Abuse Services | MO | Marta.Nolin@doc.mo.gov | (573) 522-1517 | DOC Pre-Release Pilot. |
| Marylin Gibson | Green County DWI Court | Drug Court Coordinator | MO | marilyn.gibson@courts.mo.gov | (417) 829-6620 | VIVITROL for Drug DWI Offenders; Ms. Gibson's court participated in an evaluation of VIVITROL in Drug Courts. |
| Michael Darcy | Gateway Foundation | CEO | IL | michael.darcy@gatewayfoundation.org | (312) 913-2316 | Vivitrol for probation and parole clients. |
| Mickey Williams, J.D. | St Louis Drug Court | Drug Court Administrator | MO | Keithley.Williams@courts.mo.gov | (314) 589-6702 | Court participated in Drug Court Evaluation. |
| Mickey Williams, J.D. | St Louis Drug Court | Drug Court Administrator | MO | MWillia4@courts.mo.gov | (314) 589-6702 | VIVITROL for Drug Court Offenders; Ms. Williams' court participated in an evaluation of VIVITROL in Drug Courts. |
| Patrick McCarthy, MS, LCSW, MBA | Hampden County Sheriff's Department | Director of Health Services | MA | pat.mccarthy@sdh.state.ma.us | (413) 858-0344 | VIVITROL and treatment provided to reentering offenders prior to leaving the county correctional facility and to continue into the community. |
| Randall Ambrosius | Wood County | Manager, Mental Health and AODA | WI | rambrosius@co.wood.wi.us | (715) 421-8849 | VIVITROL provided for repeat DWI offenders. |
| Randy Spangle | Ashland County | Director, Ashland County Council on AODA | WI | aac@ncis.net | (715) 682-5207 | VIVITROL provided for repeat DWI offenders . |
| Rebecca Hogamier, MBA, LCADC | Washington County, Division of Addiction and Mental Health Services | Director | MD | rhogamier@dhmh.state.md.us | (240) 313-3283 | VIVITROL provided to reentering offenders leaving the county detention center, with the first injection planned prior to release. Continuing care with VIVITROL to occur in the community. Initiative won SAMHSA Science to Service Award, 2013. |
| Rhonda Panda, BS, CAC, CCDP | Recovery Network of Programs | Drug Court Coordinator | CT | Rhonda.Panda@rnpinc.org | (203) 610-6410 Ext. 115 | Part of NEADCP Project. VIVITROL for opioid or alcohol drug court participants. |
| Rob Watson | Stone County Drug/DWI Court | Probation Officer | MO | Rob.Watson@doc.mo.gov | (417) 357-1216 | Vivitrol for Drug and DWI court clients. |
| Robin Edwards | St. Louis Drug Court | Drug Court Coordinator | MO | Robin.Edwards@courts.mo.gov | (314) 616-5102 | Vivitrol for Re-Entry initiative and newly created MAT docket. |
| Sheriff James M. Cummings | Barnstable County Sheriff's Office | Sheriff | MA | jcummings@bsheriff.net Note: Contact Jessica Burgess, MSN, RN, Asst Director Health Services, jBurgess@bsheriff.net | (508) 563-4302 | VIVITROL and treatment provided to reentering offenders prior to leaving the county correctional facility and to continue in the community post release. |
| Sheriff Peter J. Koutoujian | Middlesex County Sheriff's Office | Sheriff | MA | Note: Contact Superintendent Sean McAdam at smcadam@sdm.state.ma.us | (978) 932-3376 | VIVITROL and treatment provided to reentering offenders prior to leaving the county correctional facility and to continue in the community post release. |
| Tim Griffin | Colorado Department of Corrections | Special Project Manager | CO | tgcolorado@[redacted] | (303) 704-2410 | Vivitrol Pilot for Parole Violators. |
| Wendy McCullough | Stairways Forensics Clinic | Director | PA | wmccullough@stairwaysbh.org | (814) 878-3472 | Providing Vivitrol for alcohol and opioid dependent parole and probation clients. |

## Public Health Center - Federally Eligible 340B Settings

| Name | Affiliation | Position | State | Email | Phone | Descriptions |
|---|---|---|---|---|---|---|
| Brenda Boetel | Pennington County Sheriff's Department, City/County Alcohol and Drug Programs | Director | SD | brendab@co.pennington.sd.us | (605) 394-6128 Ext. 204 | VIVITROL for high-risk/high need patients; Medication provided at Federally Qualified Health Center (FQHC). |
| David Swann, M.A. | Crossroads Behavioral Healthcare | CEO | NC | DSwann@crossroadsbhc.org | (336) 835-1001 Ext. 1104 | VIVITROL integrated into Federally Qualified Health Center (FQHC). |
| Dorsey Ward, MSW | Carolina Medical Center | Executive Director | NC | ward@carolinashealthcare.org | (704) 283-2043 | VIVITROL provided at a Federally Qualified Health Center (FQHC). |
| Jeff Berman, MD | Bergen Regional Medical Center | Medical Director | NJ | JBerman@bergenregional.com | (201) 394-7491 | Integrated VIVITROL into a Disproportionate Share Hospital's (DSH) inpatient specialty service and large primary care services. |
| Jone Payton, RN | Portsmouth Public Health Department | Rural AIDS/Community Grants Coordinator | OH | Jone.Payton@odh.ohio.gov | (740) 353-5153 Ext. 234 | VIVITROL provided to uninsured alcohol and opioid dependent patients. |
| Mark Stanford, Ph.D. | Santa Clara County, Addiction Medicine & Therapy Division | Director | CA | Mark.Stanford@hhs.scc.gov | (408) 885-4078 | VIVITROL initiated in county jail and then subsequent doses administered in FQHC; program evaluation planned. |

## Tribal Settings

| Name | Affiliation | Position | State | Email | Phone | Descriptions |
|---|---|---|---|---|---|---|
| Ann Bruce MD | Suquamish Tribe | Medical Director | WA | abruce@suquamish.nsn.us | (360) 394-8558 | A Vivitrol program within the Suquamish Tribe, Suquamish WA, First dose delivered either in hospital post detox or in jail. |
| Dan Cable CDP | Muckleshoot Tribe | Supervisor Addictions Program | WA | dan.cable@muckleshoot-health.com | (253) 939-6648 | A Vivitrol program within the Muckleshoot tribe, Auburn WA. First dose delivered either in hospital post detox or jail. |
| Hon. Bradley Dakota | Keweenaw Bay Indian Community | KBIC Tribal Court | MI | tcbrad@up.net | (906) 353-8124 | Vivitrol being provided for tribal court clients. |
| Ted Hall, PharmD | Ho-Chunk Nation | Chief Pharmacist | WI | Ted.Hall@ho-chunk.com | (608) 355-1240 Ext. 5582 | A VIVITROL program within the Ho-Chunk Nation in Wisconsin. |

## Veterans Administration Healthcare Settings

| Name | Affiliation | Position | State | Email | Phone | Descriptions |
|---|---|---|---|---|---|---|
| Bernard J. Plansky, MD | Loyola Recovery Foundation, Inc. | Medical Director | NY | bplansky@loyolarecovery.com | (585) 203-1264 | Outpatient intervention to High Risk/High Need veterans utilizing VIVITROL coordinated with VA Patient Centered Medical Homes. |
| Donald "Hugh" Myrick, MD | Medical University of South Carolina; Ralph H. Johnson VA | Associate Chief of Staff | SC | myrickh@musc.edu | (843) 792-5212 | Utilizing VIVITROL with veterans. |
| Leonardo Rodriguez, MD | Malcom Randall VA Medical Center, Gainesville FL | Clinical Expert | FL | Leonardo.Rodriguez@va.gov | (352) 376-1611 Ext. 6875 | Utilizing VIVITROL with veterans. |
| Thomas Kosten, MD | Baylor College of Medicine; Michael E. DeBakey VA Medical | Director, Division of Alcohol & Addiction Psychiatry | TX | kosten@bcm.tmc.edu | (713) 794-7032 | Utilizing VIVITROL with veterans. |

## Community Mental Heath Centers

| Name | Affiliation | Position | State | Email | Phone | Descriptions |
|---|---|---|---|---|---|---|
| Amanda Albertsen, MD | Peninsula Outpatient Clinic | Nurse Practitioner | TN | abelkins@[redacted] | (865) 970-9800 | Community mental health centers using Vivitrol with alcohol and opioid dependence. |
| Bruce Hayden, LMHC, CAP | Banyan Health Systems | CEO | FL | bhayden@spectrumprograms.org | (305) 398-6128 | Community mental health centers using Vivitrol with alcohol and opioid dependence. |
| Dean Babcock, MSW | Wishard Health Services | Associate Vice President | IN | Dean.Babcock@wishard.edu | (317) 630-7791 | Using Vivitrol in a community mental health centers in the treatment of individuals with AD, OD and co-occurring mental health problems. |
| Dora Davis, RN | Logan/Mingo Area Mental Health | Public Health Nurse | WV | | (304) 792-7130 | Community mental health centers using Vivitrol with alcohol and opioid dependence. |
| Karen Brewer, RN | Wood County Dept. of Human Services | Public **Health** Nurse | WI | kbrewer@co.wood.wi.us | (715) 421-8863 | Community mental health centers using Vivitrol with alcohol and opioid dependence. |
| Paula Brawner | Preferred Family Behavioral Health | CEO | MO | pbrawner@pfh.org | (660) 665-1962 | Using Vivitrol in a community mental health centers in the treatment of individuals with AD, OD and co-occurring mental health problems. |

## Therapeutic Communities

| Name | Affiliation | Position | State | Email | Phone | Descriptions |
|---|---|---|---|---|---|---|
| Ken Bachach, PhD | Tarzana | VP, Clinical | CA | kbachrach@tarzanatc.org | (818) 654-3806 | Large multi-site treatment system, using Vivitrol for AD and OPD. |
| Michael Darcy | Gateway Foundation | CEO | IL | michael.darcy@gatewayfoundation.org | (312) 913-2316 | Vivitrol for clients with AD and OPD. |
| Steven Margolies, MD | Phoenix House | Medical Director, NY State Region | NY | slmargolies@phoenixhouse.org | (718) 726-8484 Ext. 3790 | Large multi-site treatment system, using Vivitrol for AD and OPD; justice system involvement. |

## Rural Settings

| Name | Affiliation | Position | State | Email | Phone | Descriptions |
|---|---|---|---|---|---|---|
| Bernard J. Plansky, MD | Loyola Recovery Foundation, Inc. | Medical Director | NY | bplansky@loyolarecovery.com | (585) 203-1264 | Outpatient intervention to High Risk/High Need veterans utilizing VIVITROL coordinated with VA Patient Centered Medical Homes. |
| Ted Hall, PharmD | Ho-Chunk Nation | Chief Pharmacist | WI | Ted.Hall@ho-chunk.com | (608) 355-1240 Ext. 5582 | A VIVITROL program within the Ho-Chunk Nation in Wisconsin. |

## Public Policy-Related Research*

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| Charles P. O'Brien, MD, PhD | University of Pennsylvania School of Medicine, Center for Addiction Studies | Director & Vice-Chair Psychiatry | PA | obrien@mail.trc.upenn.edu | (215) 222-3200 Ext.132 | Lead investigator of NIDA-sponsored, multi-site study assessing efficacy of VIVITROL with opioid dependent probationers and parolees. |
| Edward Nunes, MD | Columbia University | Professor of Clinical Psychiatry | NY | nunesed@pi.cpmc.columbia.edu | (212) 543-5581 | Investigator for the NIDA-sponsored, multi-site study assessing efficacy of VIVITROL with opioid dependent probationers and parolees. |
| Frederick Altice, MD | Yale University | Professor of Medicine | CT | frederick.altice@yale.edu | (203) 737-2883 | Co-lead investigator for a NIAAA-sponsored study of VIVITROL for reentering inmates who are HIV+ and have an alcohol problem. |
| Joshua Lee, MD | New York University | Professor of Medicine | NY | joshua.lee@nyumc.org | (212) 263-4242 | Lead investigator for a pilot study of VIVITROL for opioid dependent inmates prior to release from Rikers Island. |
| Marc Gourevitch MD, MPH | New York University | Director, Internal Medicine | NY | marc.gourevitch@med.nyu.edu | (212) 263-8553 | Published on integration of VIVITROL into a primary care practices at Gouverneur and Bellevue Hospitals (NYU). |
| Sandra Springer, MD | Yale University | Assistant Professor of Medicine | CT | sandra.springer@yale.edu | (203) 737-5530 | Lead investigator for a NIAAA-sponsored study of VIVITROL for reentering inmates who are HIV+ and have an alcohol problem. |
| Susan E. Collins, PhD | University of Washington-Harborview Medical Center | Director | WA | collinss@uw.edu | (206) 832-7885 | Conducting study of Vivitrol for homeless alcoholics. |

*Alkermes provided VIVITROL free of charge for use in these studies pursuant to the Alkermes' Investigator Initiated Trial application process.

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## IMPORTANT SAFETY INFORMATION FOR VIVITROL® (naltrexone for extended-release injectable suspension)

**INDICATIONS**
VIVITROL is indicated for:
• Treatment of alcohol dependence in patients who are able to abstain from alcohol in an outpatient setting. Patients should not be actively drinking at the time of initial VIVITROL administration.
• Prevention of relapse to opioid dependence, following opioid detoxification.
• VIVITROL should be part of a comprehensive management program that includes psychosocial support.

**CONTRAINDICATIONS**
VIVITROL is contraindicated in patients:
• Receiving opioid analgesics
• With current physiologic opioid dependence
• In acute opioid withdrawal
• Who have failed the naloxone challenge test or have a positive urine screen for opioids
• Who have exhibited hypersensitivity to naltrexone, polylactide-co-glycolide (PLG), carboxymethylcellulose, or any other components of the diluent

**WARNINGS/PRECAUTIONS**
Vulnerability to Opioid Overdose: Because VIVITROL blocks the effects of exogenous opioids for approximately 28 days after administration, patients are likely to have a reduced tolerance to opioids after opioid detoxification. As the blockade dissipates, use of previously tolerated doses of opioids could result in potentially life-threatening opioid intoxication (respiratory compromise or arrest, circulatory collapse, etc). Cases of opioid overdose with fatal outcomes have been reported in patients who used opioids at the end of a dosing interval, after missing a scheduled dose, or after discontinuing treatment. Patients and caregivers should be told of this increased sensitivity to opioids and the risk of overdose.

Any attempt by a patient to overcome the VIVITROL blockade by taking opioids may lead to fatal overdose. Patients should be told of the serious consequences of trying to overcome the opioid blockade.

**Injection Site Reaction**s: VIVITROL injections may be followed by pain, tenderness, induration, swelling, erythema, bruising, or pruritus; however, in some cases injection site reactions may be very severe. Injection site reactions not improving may require prompt medical attention, including, in some cases, surgical intervention. Inadvertent subcutaneous/adipose layer injection of VIVITROL may increase the likelihood of severe injection site reactions. Select proper needle size for patient body habitus, and use only the needles provided in the carton. Patients should be informed that any concerning injection site reactions should be brought to the attention of their healthcare provider.

**Precipitation of Opioid Withdrawal:** Withdrawal precipitated by administration of VIVITROL may be severe. Some cases of withdrawal symptoms have been severe enough to require hospitalization and management in the ICU. To prevent precipitated withdrawal, patients, including those being treated for alcohol dependence:
• Should be opioid-free (including tramadol) for a minimum of 7–10 days before starting VIVITROL.
• Patients transitioning from buprenorphine or methadone may be vulnerable to precipitated withdrawal for as long as two weeks.

Patients should be made aware of the risk associated with precipitated withdrawal and be encouraged to give an accurate account of last opioid use.

**Hepatotoxicity:** Cases of hepatitis and clinically significant liver dysfunction have been observed in association with VIVITROL. Warn patients of the risk of hepatic injury; advise them to seek help if experiencing symptoms of acute hepatitis. Discontinue use of VIVITROL in patients who exhibit acute hepatitis symptoms.

**Depression and Suicidality:** Alcohol- and opioid-dependent patients taking VIVITROL should be monitored for depression or suicidal thoughts. Alert families and caregivers to monitor and report the emergence of symptoms of depression or suicidality.

**When Reversal of VIVITROL Blockade Is Required for Pain Management:** For VIVITROL patients in emergency situations, suggestions for pain management include regional analgesia or use of non-opioid analgesics. If opioid therapy is required to reverse the VIVITROL blockade, patients should be closely monitored by trained personnel in a setting staffed and equipped for CPR.

**Eosinophilic Pneumonia:** Cases of eosinophilic pneumonia requiring hospitalization have been reported. Warn patients of the risk of eosinophilic pneumonia and to seek medical attention if they develop symptoms of pneumonia.

**Hypersensitivity Reactions:** Patients should be warned of the risk of hypersensitivity reactions, including anaphylaxis.

**Intramuscular Injections:** As with any IM injection, VIVITROL should be administered with caution to patients with thrombocytopenia or any coagulation disorder.

**ADVERSE REACTIONS**
Serious adverse reactions that may be associated with VIVITROL therapy in clinical use include severe injection site reactions, eosinophilic pneumonia, serious allergic reactions, unintended precipitation of opioid withdrawal, accidental opioid overdose, and depression and suicidality. The adverse events seen most frequently in association with VIVITROL therapy for alcohol dependence include nausea, vomiting, injection site reactions (including induration, pruritus, nodules, and swelling), muscle cramps, dizziness or syncope, somnolence or sedation, anorexia, decreased appetite or other appetite disorders. The adverse events seen most frequently in association with VIVITROL in opioid-dependent patients also include hepatic enzyme abnormalities, injection site pain, nasopharyngitis, insomnia, and toothache.

**PLEASE SEE THE PRESCRIBING INFORMATION, AND MEDICATION GUIDE. PLEASE REVIEW THE MEDICATION GUIDE WITH YOUR PATIENTS.**

Substance Abuse and Mental Health Services Administration
SAMHSA ADVISORY
www.samhsa.gov • 1-877-SAMHSA-7 (1-877-726-4727)



# An Introduction to Extended-Release Injectable Naltrexone for the Treatment of People With Opioid Dependence

The U.S. Food and Drug Administration (FDA) approved extended-release injectable naltrexone (Vivitrol) in October 2010 to treat people with opioid dependence. This medication provides patients with opioid dependence the opportunity to take effective medication monthly, as opposed to the daily dosing required by other opioid dependence medications (i.e., methadone, buprenorphine, oral naltrexone). Extended-release injectable naltrexone was approved by FDA in 2006 to treat people with alcohol dependence.

Treatment of opioid dependence remains a national priority. According to the 2010 *National Survey on Drug Use and Health*, approximately 359,000 individuals reported either dependence on or abuse of heroin, and 1.92 million individuals reported either dependence on or abuse of prescribed painkillers.[1] *The Treatment Episode Data Set* (TEDS) reports that between 1998 and 2008 the percentage of individuals ages 12 and older who entered substance abuse treatment because of pain reliever abuse increased more than fourfold—from 2.2 percent to 9.8 percent.[2]

This *Advisory* provides behavioral health professionals—including substance abuse treatment specialists—and primary care medical providers (who treat people with opioid dependence) with an introduction to extended-release injectable naltrexone. It includes succinct information about extended-release injectable naltrexone, how it compares with other medication-assisted treatment (MAT) options, and clinical strategies that may be used to select, initiate, and administer treatment.

## What Role Can Extended-Release Injectable Naltrexone Play in the Treatment of Opioid Dependence?

Extended-release injectable naltrexone is another pharmacological tool that is approved for treatment of people with opioid dependence. Over the years, medications have been successful in treating many patients with opioid dependence. Methadone has been used to treat patients for decades and has been proven effective.[3] However, methadone must be dispensed to the patient at a Substance Abuse and Mental Health Services Administration (SAMHSA)-certified opioid treatment program (OTP) facility—with daily doses provided at the clinic—until the patient is deemed stable enough to receive take-home doses. Barriers to accessing this treatment include limited geographical locations of OTPs, transportation difficulties, and policies that preclude the use of methadone.

Buprenorphine, approved in 2002 by FDA to treat opioid dependence, is available at OTPs but is most often prescribed by physicians in office-based settings. Thus, in theory, it can be more accessible than methadone. However, to prescribe buprenorphine, physicians need limited special training and so all physicians may not currently be able to prescribe it. Physicians also need to be granted a waiver by the U.S. Drug Enforcement Agency (DEA) from regulations that otherwise prohibit them from treating people with opioid dependence in office settings and, at maximum, can only treat up to 100 patients at a time. Currently, mid-level practitioners (e.g., nurse practitioners, physician assistants) are not eligible for DEA waivers to prescribe buprenorphine.

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Naltrexone can be prescribed by any healthcare provider who is licensed to prescribe medications. Special training is not required; the medication can be administered in OTP clinics. Practitioners in community health centers or private office settings can also prescribe it for purchase at the pharmacy. These factors may improve access to treatment for opioid dependence.

Naltrexone requires that patients be abstinent from opioids for a period prior to induction. Such abstinence can be difficult for patients to achieve. Retention in treatment has sometimes been problematic when patients are asked to adhere to daily doses of oral naltrexone.[4] A monthly injection of naltrexone, instead of daily dosing, may improve patients' adherence to their medication regimens.[5,6]

Extended-release injectable naltrexone has a higher pharmacy cost than buprenorphine and methadone, but some data suggest that its use may reduce inpatient admissions, emergency room visits, and other health system costs.[7] Nonetheless, the higher pharmacy cost of extended-release injectable naltrexone may limit access for patients who lack health insurance or other financial resources.

## How Does Extended-Release Injectable Naltrexone Differ From Other Forms of MAT for Opioid Dependence?

Both methadone and buprenorphine are controlled substances, whereas naltrexone is not. Methadone is an opioid agonist, buprenorphine is a partial opioid agonist, and naltrexone is an opioid antagonist.

Different types of opioid receptors—or molecules to which opioid compounds attach themselves and exert their effects—are present in the brain. Agonists are drugs that activate these receptors, binding to them and producing an effect. Opioids such as methadone, morphine, and heroin are full agonists and have the greatest abuse potential. Antagonists also bind to opioid receptors, but rather than producing an effect, they block the effects of opioid compounds. Partial agonists bind to the receptors and activate them, but not to the same degree as full agonists.[8]

Naltrexone has no abuse potential, whereas methadone and buprenorphine do. Further information about the pharmacology of methadone can be found in Treatment Improvement Protocol (TIP) 43: *Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs*.[9] Additional information about buprenorphine is available in TIP 40: *Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction*.[8]

Some physicians are reluctant to prescribe agonists to treat opioid dependence because of their treatment philosophies, difficulties in tapering patients off these medications, or the potential for illicit diversion of agonist medications.[5] Physicians with these concerns may be more comfortable prescribing an antagonist, such as naltrexone, rather than agonists.

Exhibit 1 summarizes key differences between extended-release injectable naltrexone, buprenorphine, and methadone.

## How Does Extended-Release Injectable Naltrexone Work?

Naltrexone is an opioid antagonist, a medication that binds to and effectively blocks opioid receptors.[8,10] It prevents receptors from being activated by agonist compounds, such as heroin or prescribed opioids, and is reported to reduce opioid cravings and to prevent relapse.[11,12] Patients need to be informed that this medication will prevent them from feeling the euphoric effect or pain relief they previously felt when they took an opioid.[10,13,14]

## Are There Safety Concerns About Extended-Release Injectable Naltrexone?

### Risk of accidental opioid overdose and death

Accidental overdoses and overdose-related deaths have occurred among patients who have taken opioids while being treated for opioid dependence with naltrexone-containing products—including both the extended-release injectable formulation and the daily oral formulation.[15,16] Overdoses and overdose-related deaths are also a risk with

agonist therapies. No comprehensive mortality data are yet available about extended-release injectable naltrexone, but cases of fatal opioid overdose have been reported in patients who:

- Used opioids at or near the end of the 1-month dosing interval.
- Used opioids after missing a dose of extended-release injectable naltrexone.
- Attempted to overcome the opioid blockade.[10]

Patients who have been treated with extended-release injectable naltrexone may have reduced tolerance to opioids and may be unaware of their potential sensitivity to the same, or lower, doses of opioids that they used to take. If patients who are treated with extended-release injectable naltrexone relapse after a period of abstinence, it is possible that the dosage of opioid that was previously used may have life-threatening consequences, including respiratory arrest and circulatory collapse.[10]

Physicians have an obligation to educate patients who are treated with naltrexone-containing products about mortality risks that exist during and after leaving treatment for opioid dependence.[13,17] Behavioral health providers may play a role in reminding patients of these risks. It is recommended that providers and patients develop a relapse prevention plan that includes strategies to decrease the risks if relapse occurs. If patients continue to use opioids during treatment, transition to agonist medications may be considered to reduce mortality risk, although these medications also have mortality risks.[13,17]

## Risk of precipitating withdrawal

Naltrexone displaces heroin or prescribed opioids from receptors to which they have bound, which can precipitate withdrawal symptoms.[8,20] Therefore, complete detoxification from opioids before initiating or resuming extended-release injectable naltrexone is necessary to prevent withdrawal. At least 7–10 days without opioid use is recommended before beginning extended-release injectable naltrexone.[10,16]

### Exhibit 1: Key Differences Between Medications Used To Treat Patients With Opioid Dependence

| Prescribing Considerations | Extended-Release Injectable Naltrexone | Buprenorphine | Methadone |
|---|---|---|---|
| **Frequency of Administration** | Monthly | Daily | Daily |
| **Route of Administration** | Intramuscular injection in the gluteal muscle by healthcare professional. | Oral tablet or film is dissolved under the tongue. Can be taken at a physician's office or at home. | Oral (liquid) consumption usually witnessed at an OTP, until the patient receives take-home doses. |
| **Restrictions on Prescribing or Dispensing** | Any individual who is licensed to prescribe medicine (e.g., physician, physician assistant, nurse practitioner) may prescribe and order administration by qualified staff. | Only licensed physicians who are DEA registered and either work at an OTP or have obtained a waiver to prescribe buprenorphine may do so. | Only licensed physicians who are DEA registered and who work at an OTP can order methadone for dispensing at the OTP. |
| **Abuse and Diversion Potential** | No | Yes | Yes |
| **Additional Requirements** | None; any pharmacy can fill the prescription. | Physicians must complete limited special training to qualify for the DEA prescribing waiver. Any pharmacy can fill the prescription. | For opioid dependence treatment purposes, methadone can only be purchased by and dispensed at certified OTPs or hospitals. |

Sources: Adapted from [16,18,19]

## Adverse events

The most frequently reported adverse events include hepatic enzyme abnormalities, injection site pain, common cold symptoms, insomnia, and toothache. Nausea, vomiting, muscle cramps, dizziness, sedation, decreased appetite, and an allergic form of pneumonia have also occurred in people treated with extended-release injectable naltrexone.[10,21]

### Injection site reactions

Injection site reactions—including pain, hardness, swelling, blisters, redness, bruising, abscesses, and tissue death—have been reported to FDA. Some reactions are serious enough that surgery is needed.[16]

To reduce the risk of serious injection site reactions:

- Extended-release injectable naltrexone should be administered as an intramuscular injection into the gluteal muscle using the specially designed administration needle provided. It should never be administered intravenously, subcutaneously, or inadvertently into fatty tissues.
- Extended-release injectable naltrexone should be administered into alternating buttocks (sides of the patient) each month.
- Healthcare providers should consider alternate treatments for patients whose body size, shape, or posture makes it impossible to administer extended-release injectable naltrexone in the recommended location. Note that the needle provided is not a standard needle (see last bullet). It is not possible to substitute a standard needle of a longer length.
- Patients who develop injection site reactions that do not improve should be referred to a surgeon.
- The packaging of extended-release injectable naltrexone was changed in 2010. Both 1.5- and 2-inch needles are included for injecting the medication, to accommodate patients' different body sizes. Use the 2-inch needle for most patients and reserve the shorter needle for lean patients.[10,16]

### Liver adverse effects

The FDA requires warnings on formulations of naltrexone about possible liver adverse effects. The current product labeling for extended-release injectable naltrexone includes a warning about hepatotoxicity when the medication is given in more than the recommended dose. Use of the medication is contraindicated in patients with acute hepatitis or liver failure. The medication manufacturer states that the margin of separation between the apparently safe dose and the dose causing hepatic injury appears to be only fivefold or less.[10] Extended-release injectable naltrexone should be discontinued if signs or symptoms of hepatitis develop (e.g., fatigue, loss of appetite, nausea, vomiting, abdominal pain, gray-colored bowel movement, joint pain, jaundice).[10] Further research and postmarket surveillance are underway to determine any long-term effects of this formulation on the liver.

## Which Patients May Benefit Most From Treatment With Extended-Release Injectable Naltrexone?

It is difficult to predict which medication will work for a particular patient with opioid dependence. Factors affecting a patient's treatment success with a medication may change over time or with subsequent treatment attempts. Extended-release injectable naltrexone benefits people with opioid dependence who are at risk for opioid use immediately after detoxification.[6] People facing periods of greatly increased stress or other relapse risks (e.g., visiting places of previous drug use, loss of spouse, loss of job) may find they benefit from the reassurance of the blockade provided by the medication.[11,13] People who have a short or less severe history of dependence may also want to consider injectable naltrexone.[6] Still others may have to demonstrate to professional boards, supervisors, drug court judges, or other authorities that their risk of using a nonprescribed opioid is low and the extended-release formulation may provide an option that has reduced risk compared with other options. No definitive research is available that states which patients would most benefit from extended-release injectable naltrexone, but the following people may be good candidates for treatment.

### People who have not had treatment success with methadone or buprenorphine

Depending on the reasons for treatment failure, people with opioid dependence who have not been successful with treatment with methadone or buprenorphine may benefit from extended-release injectable naltrexone.[22]

### People who have a high level of motivation for abstinence

People who are highly motivated to achieve and maintain abstinence from opioids may be good candidates for extended-release injectable naltrexone.[12,23] This includes people who are required to demonstrate abstinence with drug screens, such as individuals in impaired healthcare provider programs, parolees, probationers, and airline pilots.[24] Preliminary results from an ongoing study of U.S. healthcare professionals with opioid dependence suggest that this treatment can be successful for up to 1 year.[25]

### People successful on agonists who wish to change their medication or patients not interested in agonist therapy to treat their opioid dependence

Some patients may be successful on agonist treatment and want continued pharmacologic help to prevent relapse but would prefer another type of treatment,[22] while other patients may never be interested in agonist therapy. These types of patients could include individuals who:

- Feel they are discriminated against, or are embarrassed or ashamed, because they are on methadone maintenance or who previously experienced these emotions while undergoing methadone therapy.[26]
- Would like to reduce the time devoted to daily or multiple OTP visits per week, as is often required for methadone treatment.[13]
- Prefer to receive office-based treatment in a primary medical care setting, rather than treatment in specialty clinics or treatment centers.[24,26]

### Adolescents or young adults with opioid dependence

Methadone or buprenorphine are not always available to treat young people with opioid dependence because of OTP facility policies or governmental regulations. However, the safety and efficacy of extended-release injectable naltrexone have not been established for patients who are younger than age 18, and use for this population is not approved by FDA. Only limited experience in treating this population with extended-release injectable naltrexone is reported in the literature.[26]

## Can Extended-Release Injectable Naltrexone Be Used With Behavioral Therapies?

For most patients with opioid dependence, medications alone are insufficient. Treatment in individual or group counseling sessions and participation in mutual-help programs are also needed. Patients have better treatment outcomes when naltrexone-based treatment is combined with behavioral therapies.[4,6,27] The efficacy of extended-release naltrexone has been established when given in conjunction with behavioral support; it has not been studied as a sole component of treatment.

Healthcare providers should be ready to offer brief intervention if patients relapse during treatment of opioid dependence. Motivational interviewing and relapse prevention strategies may also enhance the effectiveness of pharmacological treatments.[8]

## How Can Pain Be Treated During or After Extended-Release Injectable Naltrexone Treatment?

Pain management in people receiving all forms of MAT, including extended-release injectable naltrexone, can be challenging. Some people can be safely and effectively treated with nonpharmacologic remedies, such as physical therapy, massage, or acupuncture, as long as the injection site is protected. Pain relief may also be obtained from nonopioid topical medications, nonsteroidal anti-inflammatory agents, regional blocks,

and nonopioid painkillers such as gabapentin and atypical antidepressants.[13]

Use of opioid-containing analgesics may aggravate preexisting addiction disorders and cause relapse. People with opioid dependence who require opioid therapy for chronic pain should be managed by pain management specialists. In light of its antagonist property, extended-release injectable naltrexone may not be appropriate for these patients.[22]

## Reversing blockade of opioid receptors

There are few clinical trial data available about reversing the opioid receptor blockade. When surgeries or procedures are planned for patients who use extended-release injectable naltrexone, it may be safest to delay the procedure until naltrexone blood levels are low enough to restore opioid receptor availability. The manufacturer of extended-release injectable naltrexone also suggests considering use of regional analgesia or nonopioid analgesics.[10]

In emergencies, it is possible for healthcare providers to reverse extended-release injectable naltrexone's opioid receptor blockade. However, higher than usual dosages of a rapidly acting opioid medication may be needed to achieve pain relief if a patient still has a tolerance to opioids. These higher dosages increase the risk of respiratory depression. Patients administered such high doses should be closely monitored by professionals trained in the use of anesthetic drugs, management of respiratory depression, and the performance of cardiopulmonary resuscitation.[10,16]

Patients who are treated with extended-release injectable naltrexone should be encouraged to wear medical alert jewelry or carry a disclosure card to help emergency personnel provide pain management safely when these patients are unconscious or cannot otherwise communicate.

# Resources

Several publications are available free of charge from SAMHSA. The resources listed below can be ordered from SAMHSA's Publications Ordering Web page at http://www.store.samhsa.gov. Or call 1-877-SAMHSA-7 (1-877-726-4727) (English and Español). Publications can also be downloaded from the Knowledge Application Program Web site at http://www.kap.samhsa.gov.

## Resources for professionals

*Substance Abuse Treatment Advisory: Naltrexone for Extended-Release Injectable Suspension for Treatment of Alcohol Dependence*. (2007). Volume 6, Issue 1. HHS Publication No. (SMA) 07-4267.

*Substance Abuse Treatment Advisory: Emerging Issues in the Use of Methadone*. (2009). Volume 8, Issue 1. HHS Publication No. (SMA) 09-4368.

Treatment Improvement Protocol (TIP) 40: *Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction*. (2004). HHS Publication No. (SMA) 07-3939.

TIP 43: *Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs*. (2005). HHS Publication No. (SMA) 08-4214.

TIP 45: *Detoxification and Substance Abuse Treatment*. (2006). HHS Publication No. (SMA) 08-4131.

## Resources for clients

*The Facts About Naltrexone for Treatment of Opioid Addiction*. (2009). HHS Publication No. (SMA) 09-4444.

*Medication-Assisted Treatment for Opioid Addiction: Facts for Families and Friends.* (2009). HHS Publication No. (SMA) 09-4443.

## Other Web resources for medical and health professionals

**National Institute on Drug Abuse, NIDAMED**
http://www.drugabuse.gov/nidamed

**U.S. Food and Drug Administration**
http://www.fda.gov

For specific information on extended-release injectable naltrexone: http://www.accessdata.fda.gov/drugsatfda_docs/label/2010/021897s005s010lbl.pdf

For specific information on adverse injection site reactions: http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm103334.htm

# Notes

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## *SAMHSA Advisory*

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**From:** Quyle, Lindsay
**Sent:** Friday, September 26, 2014 8:37 AM
**To:** Quyle, Lindsay;Cleveland, Bridget;Ahearn, Mark;Atkins, Chris;Bailey, Brian (OMB);Bauer, Zachary C;Berry, Adam (GOV);Brooks, Kara D;Brown, Hannah;Marshall, Sara (Cardwell);Joyner Burroughs (Cissel), Jackie;Crabtree, Chris;Craig, Lindsey M;Czarniecki, Cary (Lani);Denault, Christina;Espich, Jeff;Fritz, Pam (GOV);Jarmula, Ryan L;Kane, Kristen;Vincent, Micah;Morales, Cesar (Diego);Myers, Janille;Neale, Brian S;Pavlik, Jennifer L;Pitcock, Josh;Price, Kendra;Schilb, Veronica J;Schmidt, Daniel W;Simcox, Stephen;Streeter, Ryan T;Fernandez, Marilyn;Hodgin, Stephanie;Rosebrough, Dennis (LG);Cardwell, Jeffery;Dowd, Jaclyn (CECI);Keefer, Sean (GOV);Norton, Erin (Ladd);Johnson, Matt (GOV);Heater, Ryan;Fiddian-Green, Claire (CECI);Rosebrough, Dennis;Mantravadi, Adarsh V;Rosebrough, Dennis (LG);Workman, James D;McKinney, Ted;Bausman, David;Atterholt, Jim;Davidson, Brenden;Myers, Janille;Fox, Joseph R;McGrath, Danielle
**Subject:** [Gov Clips] Howey
**Attachments:** 9-26-14_HPI Daily.pdf

Thank you,

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# Sept. 26, 2014 HPI Daily Wire

Friday, September 26, 2014 7:54 AM

**ADVOCATES PRESS FEDS TO APPROVE HIP 2.0:** Groups that support the state's plan to expand health care coverage for low-income Hoosiers gathered in the Indiana Statehouse on Thursday to urge the federal government to approve the proposal so it can be implemented (TenBarge, *Statehouse File*). Gov. Mike Pence submitted the proposed expansion of the existing Healthy Indiana Plan earlier this year to the federal government. But although the comment period for the proposal has ended, officials at the Centers for Medicare and Medicaid Services have yet to act on the plan. The proposal – which Pence has dubbed HIP 2.0 – could cover as many as 350,000 uninsured Hoosiers. Caitlin Finnegan Priest, a spokesperson for Covering Kids and Families of Indiana, said 59 percent of the people in that group have jobs but not health care benefits. "We think this plan will achieve the greater good of coverage for Hoosiers who have nothing today," Priest said in a statement. "It's our hope that the federal government will give HIP 2.0 the green light – and we'll be ready on day one to help people understand their new health care options and get enrolled." The plan would apply to all non-disabled adults ages 19-64, who earn between 23 percent and 138 percent of the federal poverty level. In 2014, that means a maximum income of $16,105 annually for an individual and $32,913 for a family of four. HIP 2.0 would provide three plans for low-income Hoosiers, which have different levels of coverage and cost. The plan is mean to replace a Medicaid expansion that had been part of the Affordable Care Act. Congress had mandated the expansion but the U.S. Supreme Court later ruled that states couldn't be required to provide it. That's led some states – including Indiana – to offer more creative proposals. In Indiana, a number of advocacy groups have supported Pence's plan. HIP 2.0 is "Indiana's solution to the health care crisis, said Doug Leonard, the president of Indiana Hospital Association. The association was among the group that rallied Thursday to call on federal officials to approve the plan. Others included the AARP Indiana, Covering Kids and Families of Indiana, the Indiana Council of Community Mental Health Centers, Indiana Primary Health Care Association, Indiana State Medical Association and Mental Health America of Indiana. During the gathering, advocates acknowledged that CMS has no timetable for its decision. However, the Pence administration is continuing its discussions with federal officials to try to win approval for the plan. Healthcare providers said they plan to work towards enrollment in early 2015 if the program is approved.

**STUTZMAN BACKS GROUND TROOPS IN SYRIA:** Rep. Marlin Stutzman, R-3rd, said Thursday he supports sending U.S. ground troops to fight the Islamic State in Syria and Iraq. Asked in an interview at what point, if any, he would approve of the use of ground combat forces, Stutzman said, "I think we're at that point, honestly. "If we are going to engage, we need to be willing to bring down the full force of the U.S. military. … If that's what our military says it's going to take, I'm willing to support that."

Although the Pentagon has been launching airstrikes against Islamic State forces, bases and supply lines since August, President Barack Obama has vowed that he will deploy no ground combat troops to the Mideast. But in recent testimony before a Senate committee, Army Gen. Martin Dempsey, chairman of the Joint Chiefs of Staff, said he will recommend ground troops if the air campaign proves insufficient. At least a dozen members of Congress, mostly Republicans, either have indicated they favor the use of U.S. ground forces or acknowledged the necessity for them, according to news reports. During a visit to *The Journal Gazette*, Stutzman said Thursday that Congress should renew the Authorization for Use of Military Force that lawmakers approved in 2001 for U.S. attacks in Afghanistan and in 2003 for what became the Iraq War. "There is no declaration of war here," Stutzman said about the Islamic State. "That is one thing that bothers me. We haven't declared war since World War II, but we've been in a lot of wars. "I think Congress and our federal government would do itself and the American citizens a service by making stronger declarations and definitions" of wars, he said.

**RITZ ACCUSES CECI OF 'ORCHESTRATING' SBOE VOTES AGAINST HER:** Indiana State Superintendent Glenda Ritz told a radio host Wednesday that Gov. Mike Pence's Center for Education and Career Innovation, which serves as the staff of the Indiana State Board of Education, causes conflict by steering the board members to vote in opposition to her (Elliott*, Chalkbeat Indiana*). Ritz was deeply critical of CECI during a 45-minute interview with Justin Oakley on the Internet radio program "Just Let Me Teach," which is hosted at indianatalks.com. Oakley was a Martinsville teacher when he sought the Democratic nomination to challenge then-state Superintendent Tony Bennett in 2012. He bowed out of the race when Ritz, a teacher, librarian and union leader from Indianapolis' Washington Township decided to run. When Oakley asked why Ritz's relationship with the other 10 members of the state board was so contentious, she put the blame squarely on CECI. "Politics tends to enter the discussion at some point," she said. "That is what it is. I work with the state board that's appointed by the governor. CECI, I feel, is really orchestrating how they want board members to vote. That causes the conflict between myself, and what I do at the Department of Education, and the board that I serve on." Ritz said the state board tension is less about her relationships with the other board members than it is about her disagreements with Pence. "The board and I are supposed to do work together," Ritz said. "Many times I'm not sure that is the feeling that is going on. We have to delay things we might be working on in the Department of Education because CECI wants to be part of that, or set up a meeting. CECI is overseeing what the department is doing. It's not a good feeling." Lou Ann Baker, a CECI spokesman, said today in response that the organization's role is purely supportive. "We respect the superintendent and the work she and her department are doing," Baker said.

**BUTTIGIEG RETURNS HOME FROM AFGHANISTAN:** Mayor Pete Buttigieg arrived at South Bend International Airport Thursday evening to a rousing welcome after seven months serving with the U.S. Navy in Afghanistan (*WNDU-TV)*. A Navy lieutenant, Mayor Buttigieg worked as an intelligence officer in Afghanistan. He was assigned to a counterterrorism unit focusing on the intersection of drugs, finance and terrorism. A crowd of people gathered at the terminal exit, holding signs and waving American flags for his return. "I couldn't tell you how proud I've been to read the headlines, to see how many good things are going on," said Mayor Buttigieg to the crowd of cheering greeters. He thanked everyone for their messages of support and donations of school supplies for children in Afghanistan. He also took a moment to remember his fellow servicemen. "A welcome like this reminds that not everybody I was with out there got that," Buttigieg said. "Some of them had to go home the other way. So above all we just have a huge debt of gratitude for everyone who came before us -- all the veterans who are here and all the folks who are still there right now because the war's not over." Mayor Buttigieg will spend the next week settling back into life in South Bend and visiting Naval Station Great Lakes to complete final administrative procedures to end his deployment. He will officially return to work on Monday, October 6.

**HOLDER'S COMPLICATED LEGACY:** Eric H. Holder Jr., who made history as the nation's first African American attorney general and became an icon among liberals but a divisive figure to many conservatives, announced Thursday that he will resign his post (*Washington Post*). In an emotional ceremony at the White House, President Obama paid tribute to one of the last original members of his Cabinet and a close friend, calling Holder's departure "bittersweet." Holder, at one point fighting back tears, cited a series of actions he said his Justice Department took to empower the powerless, ranging from fighting for voting rights to reforming criminal sentences for low-level drug offenders. "I have loved the Department of Justice ever since, as a young boy, I watched Robert Kennedy prove during the civil rights movement how the department can — and must — always be a force for that which is right," said Holder, who plans to remain in office until his successor is confirmed. The nation's fourth-longest-serving attorney general, Holder leaves a complicated legacy, one in which the very qualities that have endeared him to liberals — such as his pursuit of legal equality for gay men and lesbians and his focus on strengthening civil rights protections — have often left him at odds with Obama's opponents. He tried to revitalize the Justice Department's Civil Rights Division and spoke with unusual candor about racial matters, becoming the chief surrogate on race for an African American president who felt less comfortable tackling the sensitive issue in public.

**HPI DAILY ANALYSIS:** Welcome home, Mayor Buttigieg. Thank you for your service.
- Brian A. Howey

*Campaigns*

**2014: BIG-MONEY DONORS HAVING IMPACT ON STATE RACES -** A small group of big-money donors is playing hard in the 2014 elections, even if none of the contests carry quite the same marquee names as just two years earlier (Associated Press). Campaign finance data collected by the state show that more than $35 million has been given to candidates and campaign committees so far this year. Of that amount, more than $13 million has come from single donations of at least $10,000. The amount of spending thus far is light by Indiana standards and reflects a relatively dormant election cycle. The top races on the ballot are for secretary of state, treasurer and auditor, a situation that occurs every 12 years. Still, major donors have found outlets for their money. Most of the money has gone to legislative races as House Republicans look to hold on to a supermajority they obtained in 2012 and Senate Republicans, who have long outnumbered Democrats, look to build on their 37-13 lead. Northwest Indiana hotel tycoon Dean White has accounted for $1.3 million alone, including three donations of $250,000 each to Republican Gov. Mike Pence, the House Republican campaign committee and Republican House Speaker Brian Bosma. Pence isn't up for re-election until 2016 but has been flirting with the idea of a White House run. House Democrats have benefited from a $250,000 donation from the Teamsters union and $175,000 from the Union of Painters and Allied Trades. Other major donations have been funneled from Wal-Mart fortune heiress Alice Walton and through conservative education groups to conservative candidates.

**2014: BEHNING TOP SPENDER -** The spending so far hasn't translated into a flood of campaign ads. The Center for Public Integrity found that Indiana candidates had spent $342,200 on advertising on Indiana broadcast networks through September. House Education Chairman Robert Behning, R-Indianapolis, spent the most of any candidate, $139,500, to fend off a union-backed challenger in the May primary. The center, which claims to be nonpartisan, reviewed data about political advertising on national cable and broadcast television in all of the country's 210 media markets. The organization used research from Kantar Media/CMAG, which tracks political advertising and offers a widely accepted estimate of the money spent to air each spot. The figures paint only a partial picture because they don't include money spent on ads on radio, online and direct mail, as well as television ads on local cable systems, or the cost of producing the messages.

**2014: WHITE PROPOSES ELECTION REFORMS -** Democratic Secretary of State candidate Beth White says she wants to improve Indiana's voter participation, which is third lowest in the country and is proposing a series of election reforms (Smith, *Indiana Public Media*). Indiana is one of only three states – along with Kentucky and Hawaii – that closes its polls as early as six P-M. Marion County Clerk Beth White, the Democrat running for Secretary of State, says extending that by even one hour is a common sense way to encourage greater voter turnout. She acknowledges that increasing poll hours will cost money. But White says that shouldn't be the greatest concern. "The most important thing to me is not elections on the cheap; it's elections that work for the people. And the crisis we have now is that people don't vote," White says. White says Indiana also needs to change the way it redraws its legislative districts every ten years. She says redistricting controlled by legislative majorities has led to more uncompetitive races and driven up voter apathy. "We need a nonpartisan commission that draws districts that are compact and have communities of interest at stake. And the way that other states have done this all around the country – other states are doing a much better job of this and we have got to improve," White says. A bill cosponsored by Speaker Brian Bosma creating a redistricting commission overwhelmingly passed the House last session, but did not get a hearing in the Senate.

*Congress*

**COATS, SENATORS URGE ECONOMIC PRESSURE ON RUSSIA:** Senator Dan Coats and eight other senators have sent a letter to Treasury Secretary Jacob Lew urging the Obama Administration to press European financial regulators to cut off Russian banks sanctioned by the European Union (E.U.) from the Society for Worldwide Interbank Financial Telecommunication (SWIFT), the global financial messaging service governed by E.U. law (*Howey Politics Indiana).* "Boosting economic pressure on Russian banks would put an effective and immediate squeeze on Russia's economy," said Coats. "Together, the United States and the European Union must act decisively to demonstrate that Putin's aggression in Ukraine is unacceptable." The letter to Secretary Lew comes on the heels of Ukrainian President Poroshenko's September 18 address to a joint session of Congress, where he called for additional economic sanctions on Russia. That same day, the European Parliament adopted a resolution that urged SWIFT to consider excluding Russia from the system. In the letter, the senators noted that SWIFT's own bylaws allow for the expulsion of a user that is subject to E.U. sanctions. Senators Mark Kirk (R-Ill.), John McCain (R-Ariz.), Marco Rubio (R-Fla.), Pat Roberts (R-Kan.), Kelly Ayotte (R-N.H.), Jeff Sessions (R-Ala.), David Vitter (R-La.) and John Thune (R-S.D.) also signed the letter.

**VISCLOSKY HONORS WWII VET:** Earl Schroeder recalled being a young soldier serving in France during World War II when he and about 160 others were invited to dine with General Dwight Eisenhower (*Post-Tribune*). The occasion — to celebrate the general's crossing from France into Germany. "I helped build the bridge that made that crossing possible," Schroeder said proudly. From there, Schroeder said U.S. troops moved into Belgium, leading to the end of the war in Europe and soon afterward his longed-for return to the United States. On Wednesday night, the Michigan City native, who now resides in California, again dined with dignitaries — this time at Teibel's restaurant to celebrate Schroeder's 95th birthday and his receiving military medals that were never issued to him. U.S. Rep. Pete Visclosky, D-1st, and state Rep. Shelli VanDenburgh, D-Crown Point, brought gifts to thank the veteran for his five years of combat service to the country. Visclosky presented Schroeder with seven medals that he was entitled to but due to an oversight had not received for his tours of duty in the European Theater and a short stint in Africa. Visclosky said it was his honor to help Schroeder and his family obtain the long-overdue medals. "So many soldiers like Earl thought it was their responsibility to serve their country back then. They didn't expect any medals," Visclosky said.

**CARSON ANNOUNCES FEDERAL GRANT TO TACKLE RECIDIVISM:** U.S. Rep. André Carson announced that Volunteers of America of Indiana is the recipient of a one million dollar grant from the Department of Justice to help reduce recidivism rates across the state (*Howey Politics Indiana*). The funds will be used to fund mentoring for mothers and fathers that are within six months of release from a correctional facility. The goal is to reduce recidivism rates by providing mentoring that focuses on family reunification, employment and training and substance abuse treatment. The Department of Justice awarded grants in several categories; however, Volunteers of America of Indiana is the only recipient in the state to receive an award in the 'Comprehensive Community-Based Adult Reentry Program Utilizing Mentors' category.

**WALORSKI TO VISIT MIAMI CO. ON EDUCATION TOUR:** U.S. Re. Jackie Walorski announced that next week she will visit Peru High School as part of her 'Hoosier Education Tour' (*Howey Politics Indiana*). Earlier this month, Walorski was scheduled to visit the school, but a closure due to weather postponed that trip. Walorski has already visited nine counties on the tour, meeting with community leaders, teachers and students to discuss ways to improve opportunities that will prepare northern Indiana students for a globally competitive workforce. Tuesday, Sept. 30th 9:30 a.m. – Walorski will tour Peru High School and visit the Peru Community Schools Art Gallery, a permanent art gallery, courtesy of a Peru High School alumnus, that is a world-class, original art collection consisting of paintings from Pablo Picasso to 54 pieces of oriental art. Peru High School, 401 N. Broadway, Peru.

**STUTZMANS APPEAR ON TLC SHOW:** Christy Stutzman, wife of Congressman Marlin Stutzman, made a surprise appearance last night on the TLC reality show, 19 Kids and Counting (*Fort Wayne Journal Gazette*). Christy Stutzman co-owns Ava Laurenne Bride in Fredericksburg, Va. with her sister Wendy Rivera, and Jill Duggar visited to find a wedding dress. Jill Duggar is the first Duggar daughter to get married and the wedding has been a key storyline this year. The Stutzman's busily tweeted last night during the show. Christy Stutzman posted "It was such an honor and a joy, @jillmdillard You are such a beautiful, Godly lady inside and out! Sweet episode!" And Marlin Stutzman chimed in with "Watching #19kidsandcounting What a great way to spend time with family before some big weddings!"

*General Assembly*

**'PUBLIC INTEGRITY COALITION' TO ANNOUNCE PROPOSAL:** The Public Integrity Coalition has developed a legislative proposal to address some of the issues that arise when public funds are misappropriated from local government offices (*Howey Politics Indiana*). The Attorney General's Office, which serves as the state's collection agent when officials are required to repay misappropriated funds, helped organize the Public Integrity Coalition. The coalition's proposed legislation will be announced at the news conference Friday which will include Indiana Attorney General Greg Zoeller, Matthew C. Greller., Executive Director and CEO of the Indiana Association of Cities and Towns, David Bottorf, Executive Director of the Association of Indiana Counties, and Paul Joyce, CPA/State Examiner with the State Board of Accounts . 10:30 a.m. Friday, Attorney General's Office, Statehouse, Indianapolis.

**DELANEY ASKS FOR TOUGHER ETHICS RULES AFTER TURNER:** An Indiana House Democrat is calling for a new ethics rule designed to close loopholes exposed by departing Republican House Speaker Pro Tem Eric Turner (*Associated Press*). Rep. Ed DeLaney of Indianapolis issued a letter to media outlets Wednesday saying lawmakers should enact a new "Turner Rule" that bars them from "any legislative activity" on issues in which they have money at stake. During private meetings of House Republicans this year, Turner fought legislation that would have halted construction of nursing homes, skirting state ethics rules on conflicts of interest. An Associated Press investigation found his family's nursing home business, Mainstreet Property Group, stood to lose millions of dollars in possible profit if a construction ban was approved. Turner has repeatedly denied any wrongdoing. He announced last week that he would

resign in November if re-elected, but has rejected calls from his opponent, Democrat Bob Ashley, to step down now immediately. Under election law, it is too late for Turner's name to be removed from the ballot. If Turner, R-Cicero, does win, a caucus of precinct committee officials in District 32 will choose his replacement. The House Ethics Committee cleared Turner of wrongdoing in April but determined he exposed loopholes in state ethics laws. Republican House Speaker Brian Bosma announced last month that he would remove Turner from leadership and work on ethics reforms during the 2015 session. DeLaney said the case illustrates the need to broaden the House rule governing self-interest, which he said was too specific. "This rule forbids speaking and voting on matters of serious personal financial interest. It should be expanded to expressly forbid any legislative activity on a matter seriously affecting oneself, including lobbying one's fellow members," Delaney wrote. He said that by making his case during caucus discussions, Turner in effect became a lobbyist, not a legislator. Turner said he was taking a job with Equip Leadership Inc., a Georgia-based not-for-profit organization specializing in mentoring and equipping Christian leaders.

**REP. DERMODY LEADS PUBLIC POLICY STUDY COMMITTTEE:** State Representative Tom Dermody (R-LaPorte) led the first meeting of the Interim Study Committee on Public Policy on Thursday at the Statehouse. Rep. Dermody serves as Chairman of the committee (*Howey Politics Indiana*). "The purpose of this first meeting was for the committee to establish a basis of understanding about gaming in Indiana," said Rep. Dermody. "We all need to be on the same page when it comes to this issue in order to best determine if any actions are needed for our state." The committee took public testimony and heard an overview of Indiana's gaming laws in addition to a report regarding trends in the state's gaming revenues. The committee also discussed the economic impact of the gaming industry in Indiana as well as competitive issues the industry faces. "It is inevitable that the issue of gaming will be discussed this session with the creation of the state's biennial budget, so it was important to me that we covered the history of gaming and where the industry stands today," said Rep. Dermody. "This knowledge will help guide us into our next meeting where we will discuss if action is necessary to make Indiana casinos more competitive with out-of-state rivals." The next meeting of the Interim Study Committee on Public Policy will take place on Wednesday, Oct. 8 at 10 a.m. at the Statehouse.

*State*

**GOVERNOR: PENCE'S SCHEDULE -** 10:30 a.m. – Governor Pence to offer a prayer for U.S. American Pastor Saeed Abedini, who has been unjustly detained in an Iranian

prison for nearly two years, as part of a vigil at the Indiana Statehouse. Indiana Statehouse, South Atrium, 200 W. Washington Street, Indianapolis.

**STATEHOUSE: DCS WORKERS SUE FOR OVERTIME -** Two Indiana Department of Child Services investigators say in a federal court lawsuit that they have had to work extensive overtime without receiving required overtime pay (*Network Indiana*). Arlene Nunez and Veronica Martinez work as family case managers for the DCS office in Gary. Their lawsuit filed in federal court in Hammond says they often worked outside of regular office hours, responding to emergencies, and were forced to work through their lunch hours. The court document states that when the women complained to their supervisors about having to work during their lunch breaks, they were told: "Don't even bring it up." Attorney Adam Sedia says the state agency should be held to the same standards as other employers. He said they have evidence that other DCS employees in other cities may have received similar treatment, and he is asking that the lawsuit be considered as a "collective action" lawsuit. "Then DCS would have to disclose all other employees within the class as defined by the court. Then we would contac them and each of those members could opt in," Sedia says. DCS spokesman James Wide says he cannot comment on pending litigation. No date has yet been set for an initial court hearing on the lawsuit.

**STATEHOUSE: UNEMPLOYMENT AGENCY GETS GRANT TO COMBAT FRAUD -** Indiana's unemployment agency is receiving nearly $1.5 million from the federal government to help catch those who collect unemployment while still working (*Associated Press).* The money is coming to the Indiana Department of Workforce Development from the U.S. Department of Labor. Unemployment agency spokesman Joe Frank says the funds will be used to implement a new software system that allows Indiana to share data with all 49 other states to cross-reference items such as Social Security numbers to make sure people who work in one state aren't collecting unemployment in another. Frank says Indiana previously had the ability to catch such people within the state, but not across state lines. The money also will go toward software that works with the federal government to expedite unemployment benefits for veterans.

**STATEHOUSE: ZOELLER ORGANIZES RX 'TAKE-BACK' DAY** - Hoosiers looking to dispose of any unused or unwanted medications are encouraged to participate in the National Prescription Drug Take-Back Day on Saturday (TenBarge, *Statehouse File*). Indiana Attorney General Greg Zoeller said Indiana residents need to remember that more than half of people who abuse prescription painkillers for the first time say they

report obtaining the drugs from friends and family. "Over the years, Take-Back Days have proven to be one of the best times to clean out the medicine cabinet and get rid of old, unused prescription drugs," Zoeller said in a statement. "Keeping unneeded drugs around the house invites the possibility of misuse or abuse, and can be especially dangerous if there are young children or teens in the home."

**EDUCATION: PRE-K PILOT PROGRAM LEADERS MEET -** Representatives from the five selected counties for the state's pre-kindergarten pilot program met for the first time Wednesday to share innovative work and best practices to improve early education (Clark*, Statehouse File*). "I am profoundly grateful for the efforts of these local stakeholders who, along with the state, are staunchly committed to providing high quality early educational opportunities to our most at-risk children," Gov. Mike Pence said in a statement.State officials chose the five counties – Allen, Jackson, Lake, Marion and Vanderburgh – from among 18 finalists that had applied to be among the first to receive state funding under a law the General Assembly passed this year. The pilot program will fund pre-kindergarten programs delivered by accredited private and public schools or by community-based programs that have achieved Level 3 or 4 in the state's Paths to QUALITY voluntary childcare quality rating system. State officials say the program could provide pre-K classes for anywhere between 1,000 and 4,000 low-income children. The number depends in part on how much private money is raised to help fund the program. To qualify, a student's family income could be no more than 127 percent of the federal poverty limit. That's about $28,380 for a family of four. "We all know that the foundations of lifelong health, behavior and learning are developed in early childhood," Pence said. "We are pleased by the progress made by this dynamic group to advance early education in their local communities." The program is on track to launch in the spring of 2015.

**EDUCATION: ISU'S STATESMAN TOWERS SLATED FOR DEMOLITION -** The Statesman Towers at Indiana State University are slated for demolition, likely within the next year (Fentem, *Indiana Public Media*). ISU Vice President of Business Affairs Diann McKee says plans to redevelop the 15-story towers through an outside party have fallen through and demolition is the best option. "If any renovation or development of those properties were to occur it was going to have to be with a third party and that simply wasn't financially feasible," McKee explains. It will cost an estimated $4 million to destroy the brutalist-style towers, which have been vacant for years, save for a pair of peregrine falcons that have been nesting on the roof of one of the buildings.

**EDUCATION: EXCISE CRACKING DOWN ON COLLEGE CAMPUSES -** State excise police have been cracking down on underage drinking around college campuses across the state – and the strategy is working, if arrests are a measure (Troyer, *Statehouse File*). The excise police – which enforce the state's alcohol and tobacco laws – have logged 801 arrests or tickets related to college patrols since Aug. 1. In addition, the excise police have issued 170 administrative citations to alcohol-related businesses and have issued 79 warning tickets to individuals during the same period. "One of the most effective programs undertaken by excise officers is the Cops-in-Shops initiative, which focuses on preventing underage access to alcohol by catching minors attempting to buy alcohol with false IDs, as well as adults purchasing alcohol for minors," said Cpl. Travis Thickstun, the excise police agency's public information officer. The arrests are part of an effort to promote safety on college campuses.

**HEALTH: MEDICAL ERROR DEATHS, INJURIES DROP IN 2013 -** The Indiana State Department of Health has released its Medical Error Reporting System report for 2013 (N*etwork Indiana*). The report shows that medical staffers across the state performed 18 surgeries on the wrong patient body parts in 2013, 27 foreign objects were found in patients after surgery and two deaths or serious disabilities associated with contaminated devices were also noted. That's down from seven in 2012. The health department now reports medical errors as required by executed order issued by former Governor Mitch Daniels back in 2005. The goal of the report is to raise awareness and improve patient safety.

**HEALTH: BED SORES LEADING MEDICAL ERROR, HITS RECORD HIGH** - The latest state medical error report shows bed sores were the most reported problem again last year, with the number of incidents growing by 50 percent (*Indianapolis Business Journal*). The Indiana State Department of Health said Wednesday that hospitals and clinics reported 45 stage three or four pressure ulcers, or bed sores, acquired after admission, up from 30 in 2012. Overall, 111 medical errors were reported in 2013, the highest number in any year since the state began reporting them in 2006. "While individuals may, and do, make independent mistakes, medical errors are more often a system failure resulting from inconsistent care practices between professionals or facilities or communication lapses within or between the many health care professionals or facilities providing care to a patient," stated state health officials in their introduction to this year's report.

**ENVIRONMENT: STATE PARKS PLAN FOR VOLUNTEERS, FREE ADMISSIONS DAY -** Hoosiers can help clean up the state's parks and reservoirs this Saturday and

then come back for a free day on Sunday as part of a celebration of National Public Lands Day (*Statehouse File*). The event is the largest single-day volunteer effort for public lands. Those who want to participate can spend Saturday at any state park doing activities that include collecting wild prairie seeds for re-sowing on Department of Natural Resources properties, helping with construction projects, gardening and cleaning up trails. But National Public Lands Day isn't all work and no play. Properties will also be offering hikes, pioneer activities, crafts and live bird shows.

**ENVIRONMENT: INDIANA PLANT PLACED ON ENDANGERED LIST -** A plant that's found in part of one Indiana county is now a federally-protected endangered species (*Network Indiana*). Short's bladderpod "is in the mustard family and has small yellow flowers that will eventually produce rounded seed pods," said Mike Homoya, a botanist with the state's Department of Natural Resources. "It's found only in one small area of far southwest Posey County, not far from the confluence of the Wabash and Ohio Rivers," in southwest Indiana. The only other known locations for the plant are near Nashville, Tennessee and Lexington, Kentucky. "It's a very odd and unusual distribution for the plant, and how it's here in Indiana is a total mystery," Homoya said

**AGRICULTURE: STATE'S FARM FATALITIES DROP IN 2013 -** Indiana farm fatalities dropped in 2013 compared to the previous year, according to a Purdue University report released (Frazee, *Indiana Public Media*). The report shows there were 18 farm-related deaths in 2013, down from 26 in 2012. Contributing to fewer fatalities are a decline in the number of Indiana residents who live and work on farms; advancements in the safety, durability and productivity of agricultural equipment and reduced dependency on youth labor. The report indicates there has also been a continued decline in the number of farm fatalities involving people under the age of 21. Only one person who died in 2013 was under 21 years old. It was a 15-year-old boy who died when a tractor overturned on him in Elkhart County.

**MILITARY: CAMP ATTERBURY COMPLETES $84M EXPANSION -** Camp Atterbury has completed its expansion, which has been under construction for two years (Frazee,*Indiana Public Media*). Military officials and Gov. Mike Pence gathered today to officially open the 1,000-person barracks, dining facility, railhead and deployment center. The base's leaders say the new rail facility, in particular, will allow them to move larger loads of gear more quickly using rail cars instead of trucks. The barracks, though, do not look like traditional barracks. Instead, they look more like a college campus. "Today's youth that want to serve, I think we owe them facilities like this so we can car for them properly," says Adjutant General Martin Umbarger, :"They're giving their

ultimate sacrifice, laying their lives on the line, so I'm extremely happy that the Indiana National Guard has a facility like this." Camp Atterbury has not been housing and deploying as many troops since the wars in Iraq and Afghanistan have been drawing down, but Umbarger says the new facilities will still be used, and they will ensure the base is ready if more troops need to be deployed in the future.

Nation

**ONLY 2 OBAMA ORIGINALS LEFT:** With Eric Holder's announcement Thursday that he's stepping down as attorney general, only two original Cabinet members remain for President Obama's final White House years (*Washington Post)*. Just Education Secretary Arne Duncan and Agriculture Secretary Tom Vilsack have been with Obama since the very beginning in their original roles. Shaun Donovan has also been around the full six years, but he switched positions from secretary of housing and urban development to director of Office of Management and Budget. An aside, we had been hearing that Vilsack had one foot out the door — but his wife, Christie, may be enjoying her job here at the Agency for International Development. Asked Thursday by USA Today reporter Christopher Doering about his plans, Vilsack said: "I'm keeping the job I got because I'm not sure I can get another one."

**WHITE HOUSE: OBAMA ON 60 MINUTES -** President Obama has agreed to sit for an interview with "60 Minutes" anchor Steve Kroft, CBS News announced on Thursday (The Hill). The interview, which will tape Friday and air on the Sunday broadcast of the show, will touch on issues both foreign and domestic, the network said. It will be the president's first since the launch of airstrikes in Syria targeting Islamist militants.

**WAR: BEHEADING MILITANT IDENTIFIED -** American intelligence agencies believe they have identified the Islamic State militant who appeared on two videotapes in which American journalists were beheaded, the F.B.I. director, James B. Comey, said Thursday, but he declined to name the man while agents from the United States and Britain were searching for him (*New York Times*). Intelligence agencies have used voice-recognition technology, overhead imagery and records of Western fighters who are believed to have joined the group in the effort to identify the killer, who first appeared in a video a month ago showing the beheading of James Foley. A second gruesome video, showing the death of Steven J. Sotloff, was released about two weeks later. Both men were freelance journalists. For a while, British officials focused their suspicions on a rapper who they believed had gone to Syria to fight. Now "the

assumption is that was wrong," one official said. On Wednesday, the United States announced sanctions against a number of members of the Islamic State, including Salim Benghalem, whom it identified as a fighter "who carries out executions on behalf of the group." But he was identified as coming from France, suggesting that the two Americans were killed by someone else.

**WAR: U.S. FACES AN ASSAD DILEMMA** - President Obama said the American-led airstrikes in Syria were intended to punish the terror organizations that threatened the United States — but would do nothing to aid President Bashar al-Assad of Syria, who is at war with the same groups (*New York Times*). But on the third day of strikes, it was increasingly uncertain whether the United States could maintain that delicate balance. A Syrian diplomat crowed to a pro-government newspaper that "the U.S. military leadership is now fighting in the same trenches with the Syrian generals, in a war on terrorism inside Syria." And in New York, the new Iraqi prime minister, Haider al-Abadi, said in an interview that he had delivered a private message to Mr. Assad on behalf of Washington, reassuring him that the Syrian government was not the target of American-led airstrikes.

**FBI: COMEY BLASTS GOOGLE, APPLE** - FBI Director James B. Comey sharply criticized Apple and Google on Thursday for developing forms of smartphone encryption so secure that law enforcement officials cannot easily gain access to information stored on the devices — even when they have valid search warrants (*Washington Post).* His comments were the most forceful yet from a top government official but echo a chorus of denunciation from law enforcement officials nationwide. Police have said that the ability to search photos, messages and Web histories on smartphones is essential to solving a range of serious crimes, including murder, child pornography and attempted terrorist attacks. "There will come a day when it will matter a great deal to the lives of people . . . that we will be able to gain access" to such devices, Comey told reporters in a briefing. "I want to have that conversation [with companies responsible] before that day comes."

*Local*

**CITIES: INDY PARKS OKAY DEER HUNTING AT EAGLE CREEK -** The Indianapolis Board of Parks and Recreation approved a plan Thursday to allow the first-ever deer cull in Eagle Creek Park (Sabalow, Indianapolis Star). In a unanimous vote, the board approved a $61,000 proposal for an organization that takes disabled veterans in what's

known as a "wounded warrior" hunt to kill some deer. It would require the park to be closed to non-hunters on those days. The hunt could be held from October to January. The city also plans to hire a Purdue University-based federal wildlife management team to kill deer for a few nights when the park is closed. Typically, sharpshooters use night-vision scopes and silenced firearms. The meat would either be taken home by the hunters or donated to food banks.

**CITIES: FORMER FORT WAYNE CITY, COUNTY OFFICIAL DIES -** William G. Schnizer, a former controller at Tokheim Corp., Fort Wayne city controller and county councilman, died Wednesday night. He was 89 (Gray, *Fort Wayne Journal Gazette*). Schnizer worked for Tokheim for 43 years, becoming the company's controller. He served as the city controller from 1976 to 1980, when he called for a crackdown on unpaid parking tickets and found ways to increase the city's income by investing cash on hand in local banks that paid the highest interest rates for short-term deposits. Schnizer was elected to the County Council in 1994, a position he held until 2003.

**CITIES: MISHAWAKA SCHOOLS PLAN AFTER FAILED REFERENDUM** - Consultants say School City of Mishawaka is facing some serious debt, and are recommending strategies to improve (*WNDU-TV*).Last November, Mishawaka residents voted down a $28 million referendum by a two-to-one margin. Without the referendum, Mishawaka Schools are facing the prospect of having to save or cut $10 million by 2020. This week, the school board heard findings from a group of consultants on the state of the district. They recommended the creation of a committee to prioritize the district's needs. Terry Barker, Superintendent of School City of Mishawaka, says, "I thought the consultant gave very good recommendations. It was a good process, really appreciated the hard work that everyone put into the committee work but there aren't a whole lot of solutions out there."

**CITIES: GARY REACHES MOTOROLA DEAL FOR E-911 RADIOS -** They may have been the last to the party, but Gary city officials Wednesday approved a $2.1 million agreement with Motorola, leasing radios and other equipment to join the countywide E-911 dispatch program (Gonzalez, *Post-Tribune*). The contract for 400 portable radios and 183 mobile radios, to be installed in police and fire vehicles, will run about $1.9 million, but financing costs over the five-year lease will push the amount over $2 million, said a Motorola sales manager. The city will pay $427,305 a year beginning in October 2015. The costs of buying the equipment were set in a "master agreement" between Lake County and Motorola, said a city attorney. All but three of the 19 communities in Lake County have signed up to join the program. Once the system is

active, 911 calls will go to a dispatch center in Crown Point or, as a backup plan, to East Chicago.

**COUNTIES: HAMILTON DOMESTIC VIOLENCE SHELTER FACES SETBACK -** Community leaders pushing to open a domestic violence shelter in Hamilton County are regrouping after a key partner opted to step back into a supporting role (Davis,*Indianapolis Business Journal*). As IBJ reported last year, proponents were working on a multi-year, multimillion-dollar plan to serve residents who need emergency housing because of abuse at home—a problem officials say has been growing along with the county's population. "We still need [a shelter], and the need is only going to increase," said Noblesville Police Chief Kevin Jowitt, who is leading a core group working to advance the initiative. Early plans called for Anderson-based Alternatives Inc. to extend its services south, opening a second shelter in Noblesville.

**COUNTIES: SPARRING CONTINUES IN COURT OVER VAN TIL WITNESSES -** Federal attorneys are fighting former Lake County Surveyor George Van Til's attempt to get access to witness statements, saying they don't have to turn them over until just before his sentencing (Schultz*, Post-Tribune*). Van Til filed a motion last week saying he needed access to a witness' statements to the FBI and a grand jury because a sentencing report by the U.S. Probation Office does not give him credit for accepting responsibility. Although the sentencing report is sealed, Van Til's motion says that Probation made the decision based on the witness statements. His attorney, Scott King, says he needs to see the statements to craft a proper defense. Federal attorneys filed a response Wednesday in the U.S. District Court in Hammond, and say in it that federal rules say the evidence doesn't have to be turned over until a witness testifies during the sentencing hearing. They plan on turning over the evidence two days before his sentencing hearing, which had not been scheduled as of Thursday afternoon.

**Scott.A.Milkey**

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**From:** Nancy Hiltunen, III <chiltunen@[redacted]>
**Sent:** Thursday, September 11, 2014 9:49 AM
**To:** Guadalupe, Michele
**Cc:** Eichenberger, Daniel;McGuffee, Tyler Ann;Hahn, Trenton F. (BPAG);O'Brien Michael R.;Sladek, Brian (National Office);Mike Rinebold;Indiana Academy of Family Physicians Foundation - Missy Lewis;Mike Brady;Allison Taylor;jcaster@inaap.org;Taylor, Allison L.;Tony Gillespie;Steve McCaffrey;Herndon, Brianna;Korty, Tina;Willey, John
**Subject:** Re: Prior Authorization Forms in various states

877-580-3949, participant code [redacted]

On Sep 11, 2014, at 9:16 AM, Guadalupe, Michele <mguadalupe@arthritis.org> wrote:

> I have it on my calendar, but there isn't a call in number.
>
> Are we using same as in past weeks?
>
> Sent from my iPhone
>
> On Sep 11, 2014, at 6:38 AM, "Eichenberger, Daniel" <Daniel.Eichenberger@fmhhs.com> wrote:
>
> > Are we still meeting this morning at 10 am
> >
> > *Daniel J. Eichenberger MD, MBA*
> > *Chief Medical Officer, Chief Medical Information Officer*
> > *Floyd Memorial Hospital and Health Services*
> > *Office 812-981-6686*
> > *Cell 502-[redacted]*
> >
> > ---
> >
> > **From:** McGuffee, Tyler Ann [mailto:TAMcGuffee@idoi.IN.gov]
> > **Sent:** Wednesday, September 03, 2014 2:07 PM
> > **To:** McGuffee, Tyler Ann; Charles Hiltunen, III; Hahn, Trenton F. (BPAG); O'Brien Michael R.; Sladek, Brian (National Office); Guadalupe, Michele; Mike Rinebold; Indiana Academy of Family Physicians Foundation - Missy Lewis; Mike Brady; Allison Taylor; Eichenberger, Daniel; jcaster@inaap.org; Taylor, Allison L.; Tony Gillespie; Steve McCaffrey; Herndon, Brianna; Korty, Tina; Willey, John
> > **Subject:** RE: Prior Authorization Forms in various states
> >
> > Per IDOI General Counsel, please see the attached prior authorization form for your review.
> >
> > Thank you,
> > Tyler Ann
> >
> > -------- Original message --------
> > From: "Korty, Tina"
> > Date:09/03/2014 10:23 AM (GMT-05:00)

To: "McGuffee, Tyler Ann"
Subject: FW: TX SST – Proposed Standardized Prior Authorization Form and Rule

We need to forward this to all the people who've participated in the prior authorization discussions. If you need contact info, please let me know.

TLK

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**From:** McGuffee, Tyler Ann
**Sent:** Thursday, August 07, 2014 10:02 AM
**To:** Charles Hiltunen, III; Hahn, Trenton F. (BPAG); O'Brien Michael R.; Sladek, Brian (National Office); Guadalupe, Michele; Mike Rinebold; Indiana Academy of Family Physicians Foundation - Missy Lewis; Mike Brady; Allison Taylor;Daniel.Eichenberger@fmhhs.com; jcaster@inaap.org; Taylor, Allison L.; Tony Gillespie; Steve McCaffrey; Herndon, Brianna
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| Washington | NDCDP Study | Medical | Premera Blue Cross<br><br>Coordinated Care Health |
| Oregon | Legislation Uniform/Electronic | Medical | Moda Health<br><br>Kaiser Permanente |
| California | Legislation Uniform/Electronic | Rx only | Anthem Blue Cross<br><br>Blue Shield of California |
| Minnesota | NCPDP ePA | Rx only | Preferred One Health Insurance |

| | | | |
|---|---|---|---|
| | | | BCBS Minnesota |
| New Mexico | NCPDP ePA | Rx only | BCBS New Mexico<br><br>New Mexico Health Connections |
| New York | Legislation Uniform Only | Medicaid | Empire BCBS<br><br>Health Republic Insurance of NY |

**Scott.A.Milkey**

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**From:** Guadalupe, Michele <mguadalupe@arthritis.org>
**Sent:** Thursday, September 11, 2014 9:17 AM
**To:** Eichenberger, Daniel
**Cc:** McGuffee, Tyler Ann;Charles Hiltunen, III;Hahn, Trenton F. (BPAG);O'Brien Michael R.;Sladek, Brian (National Office);Mike Rinebold;Indiana Academy of Family Physicians Foundation - Missy Lewis;Mike Brady;Allison Taylor;jcaster@inaap.org;Taylor, Allison L.;Tony Gillespie;Steve McCaffrey;Herndon, Brianna;Korty, Tina;Willey, John
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> *Office 8*
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**Scott.A.Milkey**

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**To:** McGuffee, Tyler Ann;Charles Hiltunen, III;Hahn, Trenton F. (BPAG);O'Brien Michael R.;Sladek, Brian (National Office);Guadalupe, Michele;Mike Rinebold;Indiana Academy of Family Physicians Foundation - Missy Lewis;Mike Brady;Allison Taylor;jcaster@inaap.org;Taylor, Allison L.;Tony Gillespie;Steve McCaffrey;Herndon, Brianna;Korty, Tina;Willey, John
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*Daniel J. Eichenberger MD, MBA*
*Chief Medical Officer, Chief Medical Information Officer*
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*Office 812-981-6686*
*Cell 502-*[redacted]

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| New York | Legislation Uniform Only | Medicaid | Empire BCBS<br><br>Health Republic Insurance of NY |

**Scott.A.Milkey**

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**From:** Hill, John (DHS)
**Sent:** Monday, September 08, 2014 12:57 PM
**To:** Karns, Allison
**Subject:** FW: HEA 1006 Coalition Meeting
**Attachments:** HEA 1006 Coalition Meeting Minutes - August 28 2014.pdf; HEA 1006 Coalition - Contact List.pdf

You need to be involved in this situation. We had our first call. They are now scheduling another meeting.

---

**From:** Borchelt, Jennifer [mailto:Jennifer.Borchelt@btlaw.com]
**Sent:** Monday, September 08, 2014 12:53 PM
**To:** Naylor, Christopher W (Chris); rhull@nobleco.org; Lanham, Julie (COA); Hendrix, Jay; Watson, Ralph; Freese, Robert; mmcdaniel@kdlegal.com; Watson, William; Heath, Dave; rcook@citiesandtowns.org; jswanson@citiesandtowns.org; Emily.vanosdol@indy.gov; McGrath, Danielle; tmurtaugh@tippecanoe.in.gov; Stephanie@indianacountycommissioners.com; sluce@indianasheriffs.org; ctelliott@bosepublicaffairs.com; Hill, John (DHS); Brady, Linda; dbottorff@indianacounties.org; ABerger@indianacounties.org; llandis@[redacted]; Willey, Heather
**Subject:** HEA 1006 Coalition Meeting

Good afternoon everyone.

Attached please find the minutes from the meeting on August 28th and a contact list of those who attended.

Please let me know your availability during either of the following date/time options for the second 1 hour meeting via phone:

Wednesday, September 24th – any time between 3 – 5 pm
or
Thursday, September 25th – any time after 11 am

Once a date/time is confirmed, I will send out a conference call number.

Thanks.

Jennifer Borchelt

BARNES & THORNBURG LLP

11 South Meridian Street | Indianapolis, IN 46204
317.231.7334 – Phone
317.231.7433 – Fax

Atlanta | Chicago | Delaware | Indiana | Los Angeles | Michigan | Minneapolis | Ohio | Washington D.C.

# HEA 1006 Coalition – Contact List

| Name | Organization | Email |
|---|---|---|
| Chris Naylor | IPAC | Cnaylor1@ipac.in.gov |
| Ryan Hull | POPAI | rhull@nobleco.org |
| Julie Lanham | DOC | jlanham@idoc.in.gov |
| Jack Hendrix | IDOC | jhendrix@idoc.in.gov |
| Ralph Watson | IACCAC | Ralph.watson@hamiltoncounty.in.gov |
| Robert W. Freese | IN Judges Assoc. | rfreese@co.hendricks.in.us |
| Mike McDaniel | IN Judges Assoc. | mmcdaniel@kdlegal.com |
| Bill Watson | IACCAC | William.watson@vigocounty.in.gov |
| Dave Heath | IACCAC | dheath@tippecanoe.in.gov |
| Rhonda Cook | IACT | rcook@citiesandtowns.org |
| Justin Swanson | IACT | jswanson@citiesandtowns.org |
| Emily VanOsdol | Marion County Courts | Emily.vanosdol@indy.gov |
| Danielle McGrath | Governor's Office | dmcgrath@gov.in.gov |
| Tom Murtaugh | Tippecanoe County/IACC | tmurtaugh@tippecanoe.in.gov |
| Stephanie Yager | IACC | Stephanie@indianacountycommissioners.com |
| Steve Luce | ISA | sluce@indianasheriffs.org |
| Carolyn Elliott | ISA | ctelliott@bosepublicaffairs.com |
| John Hill | Governor's Office | jhill@gov.in.gov |
| Linda Brady | Monroe Circuit Court | lbrady@co.monroe.in.us |
| David Bottoroff | AIC | dbottorff@indianacounties.org |
| Andrew Berger | AIC | ABerger@indianacounties.org |
| Larry Landis | Public Defenders | llandis@[redacted] |
| Heather Willey | Barnes & Thornburg | Heather.willey@btlaw.com |

HEA 1006 Coalition Meeting
August 28, 2014
Barnes & Thornburg LLP

- Concerns from Community Corrections representatives that the current program is as big as it going to be without additional funding. Many counties are operating programs without any significant increases in over 8 years. Some programs have seen 150-200 offender increases in the last year without any additional appropriation. If there are not strong community correction programs the offenders will end up back in jail.
- Sheriffs' Association noted that there are some county jails with a 70% staffing deficiency. Additionally, occupancy statewide is high??
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**Scott.A.Milkey**

---

**From:** Hill, John (DHS)
**Sent:** Monday, September 08, 2014 12:57 PM
**To:** Karns, Allison
**Subject:** FW: HEA 1006 Coalition Meeting
**Attachments:** HEA 1006 Coalition Meeting Minutes - August 28 2014.pdf; HEA 1006 Coalition - Contact List.pdf

You need to be involved in this situation. We had our first call. They are now scheduling another meeting.

From: Borchelt, Jennifer [mailto:Jennifer.Borchelt@btlaw.com]
Sent: Monday, September 08, 2014 12:53 PM
To: Naylor, Christopher W (Chris); rhull@nobleco.org; Lanham, Julie (COA); Hendrix, Jay; Watson, Ralph; Freese, Robert; mmcdaniel@kdlegal.com; Watson, William; Heath, Dave; rcook@citiesandtowns.org; jswanson@citiesandtowns.org; Emily.vanosdol@indy.gov; McGrath, Danielle; tmurtaugh@tippecanoe.in.gov; Stephanie@indianacountycommissioners.com; sluce@indianasheriffs.org; ctelliott@bosepublicaffairs.com; Hill, John (DHS); Brady, Linda; dbottorff@indianacounties.org; ABerger@indianacounties.org; llandis@[redacted] Willey, Heather
Subject: HEA 1006 Coalition Meeting

Good afternoon everyone.

Attached please find the minutes from the meeting on August 28th and a contact list of those who attended.

Please let me know your availability during either of the following date/time options for the second 1 hour meeting via phone:

Wednesday, September 24th – any time between 3 – 5 pm

or

Thursday, September 25th – any time after 11 am

Once a date/time is confirmed, I will send out a conference call number.

Thanks.

Jennifer Borchelt

11 South Meridian Street | Indianapolis, IN 46204

317.231.7334 – Phone

317.231.7433 – Fax

Atlanta | Chicago | Delaware | Indiana | Los Angeles | Michigan | Minneapolis | Ohio | Washington D.C.

P Please consider the environment before printing this email.

# HEA 1006 Coalition – Contact List

| Name | Organization | Email |
|---|---|---|
| Chris Naylor | IPAC | Cnaylor1@ipac.in.gov |
| Ryan Hull | POPAI | rhull@nobleco.org |
| Julie Lanham | DOC | jlanham@idoc.in.gov |
| Jack Hendrix | IDOC | jhendrix@idoc.in.gov |
| Ralph Watson | IACCAC | Ralph.watson@hamiltoncounty.in.gov |
| Robert W. Freese | IN Judges Assoc. | rfreese@co.hendricks.in.us |
| Mike McDaniel | IN Judges Assoc. | mmcdaniel@kdlegal.com |
| Bill Watson | IACCAC | William.watson@vigocounty.in.gov |
| Dave Heath | IACCAC | dheath@tippecanoe.in.gov |
| Rhonda Cook | IACT | rcook@citiesandtowns.org |
| Justin Swanson | IACT | jswanson@citiesandtowns.org |
| Emily VanOsdol | Marion County Courts | Emily.vanosdol@indy.gov |
| Danielle McGrath | Governor's Office | dmcgrath@gov.in.gov |
| Tom Murtaugh | Tippecanoe County/IACC | tmurtaugh@tippecanoe.in.gov |
| Stephanie Yager | IACC | Stephanie@indianacountycommissioners.com |
| Steve Luce | ISA | sluce@indianasheriffs.org |
| Carolyn Elliott | ISA | ctelliott@bosepublicaffairs.com |
| John Hill | Governor's Office | jhill@gov.in.gov |
| Linda Brady | Monroe Circuit Court | lbrady@co.monroe.in.us |
| David Bottoroff | AIC | dbottorff@indianacounties.org |
| Andrew Berger | AIC | ABerger@indianacounties.org |
| Larry Landis | Public Defenders | llandis@[redacted] |
| Heather Willey | Barnes & Thornburg | Heather.willey@btlaw.com |

HEA 1006 Coalition Meeting
August 28, 2014
Barnes & Thornburg LLP

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**Scott.A.Milkey**

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**From:** Hill, John (DHS)
**Sent:** Sunday, September 07, 2014 10:46 PM
**To:** Karns, Allison
**Subject:** FW: Marion County Mental Health Project Proposal
**Attachments:** Mental Health Alternative Court-Proposal.docx

FYI…

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**From:** Berry, Adam (GOV)
**Sent:** Friday, August 15, 2014 12:17 PM
**To:** Hill, John (DHS)
**Subject:** FW: Marion County Mental Health Project Proposal

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**********

Adam H. Berry
Regulatory Policy Director & Special Counsel
Office of Governor Mike Pence
(317) 232.4567



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**From:** barbara crawford [mailto:barbaralcrawford@[redacted]]
**Sent:** Friday, August 15, 2014 8:04 AM
**To:** David Shaheed; David Certo; Lisa F. Borges; Barbara Crawford; Lloyd, Mike; Berry, Adam (GOV); Brown, Tim J. - DOC; Lanham, Julie (COA); smccaffrey@mhai.net; linda.grove-paul@centerstone.org; Seigel, Jane
**Subject:** Marion County Mental Health Project Proposal

Attached please find the proposal for the Marion County Mental Health Pilot Project

# Marion County Mental Health Alternative Court and Pilot Program

## Objective

The Marion County criminal justice system recognizes that proper intervention, medical, advisory, or rehabilitative treatment of defendants afflicted with mental illness is likely to decrease the tendency to engage in anti-social behavior. The goal of the Marion County Mental Health Alternative Court pilot program is to identify moderate to high risk individuals in the criminal justice system who have not yet been convicted and have a mental health illness that may have contributed to the commission of an offense. Once identified, those individuals will be provided with the opportunity to receive treatment and community services that would address the individual criminogenic needs each participant.

## Definitions

For purposes of this program:

Mental illness is defined as a psychiatric disorder that is of sufficient duration to meet diagnostic criteria within the most recent edition of the Diagnostic and Statistical manual or Mental Disorders published by the American Psychiatric Society. I.C. 11-12-3.7-5; Marion County Forensic Diversion Handbook.

Recidivism means the acquisition of additional criminal convictions while participating in the project or within a 12 month, 24 month or 36 month period after discharge from the project.

Service means an evidence based program or intervention designed to target one or more criminogenic needs

## Target Population

The target population for the Marion County Mental Health Pilot Project (MCMHPP) will be individuals who are designated as moderate to high risk to reoffend using the Indiana Risk Assessment System (IRAS) and have a diagnosed mental illness that is a contributing factor to the commission of a criminal offense that is a Class B/Level 4, Class C/Level 5, or Class D/Level 6 felony that qualifies under the criteria established by the Mental Health Alternative Court (MHAC). Other possible target populations that may be considered for inclusion in the project are individuals charged with a class A, B, or C misdemeanor or a class D /Level 6 felony that is not accepted by the current PAIR diversion program in Community Court, veterans who have been diagnosed with service related mental disorders, and individuals who are developmentally disabled and diagnosed with mental health disorders.

## Overview

The Marion County Mental Health Alternative Court (MCMHAC) will be a separate docket of the Marion County Court system supervised by a presiding judge of one of the courts. The MCMHAC will provide a non-adversarial adjudicative process for addressing the criminogenic needs of those individuals referred to the court. The pilot project will be a collaborative effort supervised by the Marion County Superior Courts and comprised of the following entities: Marion County Probation, Marion County Community Corrections, Marion County Prosecutors Office, Marion County Public Defenders Office, community-based behavioral healthcare agencies and/or any contractors who can provide needed services.

## Goals / Objectives

Identify 80 - 100 individuals who are charged with criminal offenses and have a diagnosed mental illness and/or co-occuring mental illness along with substance abuse. Increase the number of participants to 140 individuals within six (6) months of the opening of the MHAC. Add 80 to 100 participants each year.

Track each participant's entry into project, compliance with treatment requirements, and contact with the criminal justice system.

Select individuals to participate in the project who are moderate to high risk to reoffend based on evaluations using IRAS. These individuals will be referred from the Marion Superior Courts that preside over criminal cases.

Provide a non-adversarial adjudicative process to address the behaviors and needs of the participants.

Track the rate of recidivism of participating individuals while in the program, 12 months, 24 months, and 36 months after discharge from the project.

Reduce the rate of recidivism by 50%.

Identify other needs of each participant including medical needs, educational opportunities, access to affordable housing, assist in obtaining and maintaining employment, and referral to appropriate service providers for therapies and behavior modification programs.

Monitor participants' compliance with Mental Health Alternative Court requirements through case management and regular and frequent Court appearances.

## Eligibility

A person meeting the following criteria may be eligible to participate in mental health alternative court programs:

- A defendant has a verified mental illness that is an AXIS I disorder based on the most recent Diagnostic and Statistical Manual of Mental Disorders (DSM).
- A defendant has a mental illness that is AXIS 2-5 that is verified and can be (or has been) diagnosed by a mental health care provider or other mental health professional.
- The defendant must be charged with an offense that is:
  - Not a violent offense; and
  - Is a Class A, B, or C misdemeanor, or,
  - An offense that is a class B/Level 4 or class C/Level 5, or class D/Level 6 felony.
- Defendant must be stable.
- Defendant must be sober.
- Defendant does not have a conviction for a violent offense in the prior ten (10) years.
- Defendant has been preliminarily screened by Marion County Community Corrections or Marion County Probation Department
- Based on the IRAS assessment, Defendant is classified as moderate to high risk to reoffend.
- The court has made a determination that defendant would be an appropriate candidate for a pre-conviction program. A court may order an evaluation to determine whether a defendant is an appropriate candidate.
- The defendant has been accepted into the pre-conviction mental health program.
- The defendant has entered into a guilty plea.
- The defendant has entered into a pre-trial diversion agreement with the State.

## Participating Entities:

Marion County Mental Health Alternative Court (MCMHAC) - Mental Health Alternative Court – The assigned judicial officer would oversee each case, require each participant to appear in court periodically to determine compliance and progress. The members of the team will be accountable to the court for maintaining accurate information with regard to the status of each participant. The Court will have final say with regard to compliance, sanctions, continued participation in the program, and successful completion.

Marion County Probation Department (MCPO) – A probation officer/caseworker would assess the needs of the participant using IRAS if the participant is not in custody, obtain all necessary release of information documents from the participant, contact and coordinate treatment with the mental healthcare provider. In addition, if accepted into the program, probation would interview the participant and determine what other services would be necessary and coordinate with the mental health care provider and other community based service providers in accessing and meeting those needs. The caseworker will appear in court to provide periodic updates to the court on the progress and compliance of each participant and/or address any issues with regard to the defendant's continued participation in the program.

Marion County Community Corrections (MCCC) – If the participant is in custody, an MCCC screening analyst would provide the initial assessment of the participant, obtain necessary medical information releases from the participant, acquire relevant medical, psychological, and pharmacological information from the medical staff of the Marion County Jail. After an initial interview with the participant, a report would be generated and sent to the original trial court for use in determining whether the participant would meet the criteria for referral to the MHAC.

An MCCC caseworker would provide the same supervisory duties as the probation officer/caseworker in cases where the MHAC also orders electronic monitoring or some other form of monitoring if the MHAC determines a person should be released from the custody of the Marion County Jail. The MCCC caseworker will appear in court to provide periodic updates on the progress and compliance of each participant, and, if necessary, address any issues with regard to sanctions for violations or continued participation in the program.

Caseworkers from the probation department and MCCC will share training, programs, and resources wherever possible to maximize efficiencies in delivering services. The probation department caseworker and/or community corrections casework will be part of a team that will include the community mental healthcare provider, and any participating independent contractor in developing and implementing a treatment plan for each participant based on the participant's needs.

Community Based Health Care Providers and/or Independent Contractors

Community-based health care providers may be : Midtown Mental Health, Aspire Indiana, Gallahue, Cummins, Adult and Child, Centerstone. Participants may be referred to any of these agencies for receipt of services such as therapy and counseling, access to physicians, access to housing, educational opportunities, and/or assistance in pursuing employment opportunities. Each provider and/or contractor shall enter a memorandum of understanding with the Marion Superior Courts agreeing to keep accurate data with regard to the services provided, progress of each participant, each participant's compliance with medical and treatment requirements, the cost of services provided, and appear periodically in Court to report on the participant"s progress and compliance,

## Admission Into Mental Health Alternative Court Project

Individuals will enter the pilot by referral to the MHAC by the trial court in which the person's case is filed. If otherwise eligible, the defendant shall be required to enter a guilty plea in the court in which the charge is filed. The original court would then take acceptance of the guilty plea under advisement and transfer said case to the Mental Health Alternative Court.

The Marion County Mental Health Project and Alternative Court is a deferred prosecution program, allowing judgment to be withheld during a defendant's voluntary participation in treatment and prescribed programs and services. Speedy trial rights are waived. In order to participate in the diversion program, the participant must plead guilty to his/her charges. The treatment-based court program is a docket assigned to Marion Superior Court judicial officer. The program has the initial capacity to serve 80 - 100 participants.

Participants involved in the program voluntarily participate in treatment and case management services for a minimum of twelve (12) months to three (3) years. Under the close supervision of the Mental Health Alternative Court Judge, participants are subject to a highly structured program of rewards and sanctions; positive support and incentives are awarded by the Judge, as are sanctions for noncompliance. Initially, if approved, the participant would be in the program for a probationary period of sixty (60) days. During that time, the needs of the participant would be assessed, a treatment plan would be developed, based on those needs. The assigned case worker, mental healthcare provider, and any other participating contractor would make up the team responsible for developing the treatment plan for each participant.

At the end of 60 days, if the participant has no new convictions, has cooperated with the development of a treatment plan and voluntarily commits to abiding by the rules of the project, the participant will be officially admitted into the Mental Health Alternative Court program.

## Potential Outcomes

If a defendant successfully completes the program, the Court may:

- Waive entry of judgment of conviction and dismiss case,
- Enter judgment of conviction for a lesser offense, or
- Sentence the defendant to probation or to an alternative placement other than the Indiana Department of Corrections.

If a defendant is unsuccessful in completing the program, the case will be returned to the original trial court. The judge of the trial court will then enter an order of conviction and sentence the defendant.

Successful completion of the program will be based on the defendant's ability to demonstrate

- Compliance with the treatment program developed for the participant.
- Consistency in coming to all required court appearances.
- Absence of any subsequent criminal convictions.
- Stable living environment.
- Compliance with obtaining and taking medications.

**BUDGET**

| | Items | Cost |
|---|---|---|
| | Personnel<br>1 Caseworker – Marion County Probation Department | 150,000 |
| | 1 Caseworker – Marion County Community Corrections (includes benefits) | |
| | 1 Screening Analyst – Marion County Community Corrections (includes benefits) | |
| | Mental healthcare service providers – therapy, behavioral criminogenic issue, 2500/defendant x 50 participants | 125,000 |
| | Emergency Indigency Fund | 20,000 |
| | Supplies | 2 ,000 |
| | Consultant/Contractor – Centerstone – wrap around services and accessing community resources | 100,000 |
| | Total | |

The budget does not include amounts that will be needed for court staff for 2 docket sessions each week. In the future, there may be a request for additional funds to contract with Liberty Hall (CEC) for mental health beds for men.

The ultimate goal is to establish a sustainable, structured mental health court and program in Marion County. However, many of the components of the project described above can be implemented to get a viable program running within a short period of time.

**Scott.A.Milkey**

---

**From:** Hill, John (DHS)
**Sent:** Sunday, September 07, 2014 10:46 PM
**To:** akarns@dhs.in.gov
**Subject:** FW: Marion County Mental Health Project Proposal
**Attachments:** Mental Health Alternative Court-Proposal.docx

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Office of Governor Mike Pence

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## Admission Into Mental Health Alternative Court Project

Individuals will enter the pilot by referral to the MHAC by the trial court in which the person's case is filed. If otherwise eligible, the defendant shall be required to enter a guilty plea in the court in which the charge is filed. The original court would then take acceptance of the guilty plea under advisement and transfer said case to the Mental Health Alternative Court.

The Marion County Mental Health Project and Alternative Court is a deferred prosecution program, allowing judgment to be withheld during a defendant's voluntary participation in treatment and prescribed programs and services. Speedy trial rights are waived. In order to participate in the diversion program, the participant must plead guilty to his/her charges. The treatment-based court program is a docket assigned to Marion Superior Court judicial officer. The program has the initial capacity to serve 80 - 100 participants.

Participants involved in the program voluntarily participate in treatment and case management services for a minimum of twelve (12) months to three (3) years. Under the close supervision of the Mental Health Alternative Court Judge, participants are subject to a highly structured program of rewards and sanctions; positive support and incentives are awarded by the Judge, as are sanctions for noncompliance. Initially, if approved, the participant would be in the program for a probationary period of sixty (60) days. During that time, the needs of the participant would be assessed, a treatment plan would be developed, based on those needs. The assigned case worker, mental healthcare provider, and any other participating contractor would make up the team responsible for developing the treatment plan for each participant.

At the end of 60 days, if the participant has no new convictions, has cooperated with the development of a treatment plan and voluntarily commits to abiding by the rules of the project, the participant will be officially admitted into the Mental Health Alternative Court program.

## Potential Outcomes

If a defendant successfully completes the program, the Court may:

- Waive entry of judgment of conviction and dismiss case,
- Enter judgment of conviction for a lesser offense, or
- Sentence the defendant to probation or to an alternative placement other than the Indiana Department of Corrections.

If a defendant is unsuccessful in completing the program, the case will be returned to the original trial court. The judge of the trial court will then enter an order of conviction and sentence the defendant.

Successful completion of the program will be based on the defendant's ability to demonstrate

- Compliance with the treatment program developed for the participant.
- Consistency in coming to all required court appearances.
- Absence of any subsequent criminal convictions.
- Stable living environment.
- Compliance with obtaining and taking medications.

**BUDGET**

| | Items | Cost |
|---|---|---|
| | Personnel<br>1 Caseworker – Marion County Probation Department | 150,000 |
| | 1 Caseworker – Marion County Community Corrections (includes benefits) | |
| | 1 Screening Analyst – Marion County Community Corrections (includes benefits) | |
| | Mental healthcare service providers – therapy, behavioral criminogenic issue, 2500/defendant x 50 participants | 125,000 |
| | Emergency Indigency Fund | 20,000 |
| | Supplies | 2 ,000 |
| | Consultant/Contractor – Centerstone – wrap around services and accessing community resources | 100,000 |
| | Total | |

The budget does not include amounts that will be needed for court staff for 2 docket sessions each week. In the future, there may be a request for additional funds to contract with Liberty Hall (CEC) for mental health beds for men.

The ultimate goal is to establish a sustainable, structured mental health court and program in Marion County. However, many of the components of the project described above can be implemented to get a viable program running within a short period of time.

**Scott.A.Milkey**

**From:** Quyle, Lindsay
**Sent:** Thursday, August 28, 2014 8:39 AM
**To:** Quyle, Lindsay;Cleveland, Bridget;Ahearn, Mark;Atkins, Chris;Bailey, Brian (OMB);Bauer, Zachary C;Berry, Adam (GOV);Brooks, Kara D;Brown, Hannah;Marshall, Sara (Cardwell);Joyner Burroughs (Cissel), Jackie;Crabtree, Chris;Craig, Lindsey M;Czarniecki, Cary (Lani);Denault, Christina;Espich, Jeff;Fritz, Pam (GOV);Jarmula, Ryan L;Kane, Kristen;Vincent, Micah;Morales, Cesar (Diego);Myers, Janille;Neale, Brian S;Pavlik, Jennifer L;Pitcock, Josh;Price, Kendra;Schilb, Veronica J;Schmidt, Daniel W;Simcox, Stephen;Streeter, Ryan T;Trexler, Christina;Fernandez, Marilyn;Hodgin, Stephanie;Rosebrough, Dennis (LG);Cardwell, Jeffery;Dowd, Jaclyn (CECI);Keefer, Sean (GOV);Norton, Erin (Ladd);Johnson, Matt (GOV);Heater, Ryan;Fiddian-Green, Claire (CECI);Rosebrough, Dennis;Mantravadi, Adarsh V;Rosebrough, Dennis (LG);Workman, James D;McKinney, Ted;Bausman, David;Atterholt, Jim;Davidson, Brenden;Myers, Janille;Fox, Joseph R;McGrath, Danielle
**Subject:** [Gov Clips] Howey
**Attachments:** 8-28-14_HPI Daily.pdf

Thank you,

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# August 28, 2014 HPI Daily Wire

Thursday, August 28, 2014 7:37 AM

**BAYH'S GOV. DECISION WILL HAVE LONG-RANGE REPERCUSSIONS:** Sometime between Labor Day and Sept. 10 when he appears at a Northwest Indiana One Region event, Evan Bayh is expected to make a decision that will have emphatic political ramifications for Indiana over the next decade (Howey, *Howey Politics Indiana*). The decision is whether he will seek a third term as governor. It will be as important as the 2002 decision Mitch Daniels made to enter the 2004 gubernatorial race, or Bayh's 1987 decision to run for the first time. Both those decisions ushered in more than a decade of political dominance, with Bayh igniting a 16-year Democratic gubernatorial dynasty that included terms by Frank O'Bannon and Joe Kernan, and Daniels' decision that cued up a 12-year run for the GOP that extends to this very day. Current conventional wisdom that dominated the Indiana Democratic Editorial Association convention last weekend in French Lick was that Bayh won't run. In a July interview with CNHI and HPI's Maureen Hayden, Bayh called a run "unlikely," and repeated that assertion on WFYI's "No Limits" program last week. The probable calculus running through Bayh's mind are the two super majority legislative chambers where Republicans hold a 69-31 House advantage and 37-13 in the Senate that would make governing tough. He cited "polarization" in questioning whether he could effectively govern in a job he has always called the best times of his career. It is a far cry from the 50/50 House chamber that greeted his first year in office in 1989 and the slim Democratic majorities thereafter. Reacting to a potential bid have been Republicans who assert with dogged determination that Bayh won't run, essentially asking, "Why would he want to do that?" The profound wishing in GOP camps that Bayh won't run is pronounced whistling past the graveyard. If Bayh were to run, the GOP's 12-year hold on the governor's office would be in real jeopardy. Bayh is the one Democrat who could clear the field, raise mega bucks, and make a credible appeal to moderates and independents who decide Indiana elections. However, other influential Democratic sources tell HPI they are not sure Bayh has made a decision. "I would hope that is the case," said Hammond Mayor Thomas McDermott Jr., who along with John Gregg are planning 2016 runs, but have seen money hard to raise as long as Bayh is potentially in the equation. "Otherwise why wouldn't he have announced he wasn't running by now?" Another influential Democrat, speaking on background, told HPI, "I'm not sure he knows." This Democrat makes the case that Bayh's doubts about his effectiveness in the face of daunting Republican majorities doesn't take into account the former governor's own track record of igniting what he called the "white hot heat of public opinion" when seeking policy initiatives often opposed by a hostile Senate Republican majority during his eight years in office. "He has had the ability to go to the public and get support in places like Rochester," this Democrat said. "He consistently talked about the need for consensus. He has the unique ability to build that consensus with moderates and independents." With Bayh on the ticket, his long coattails pulled in between three and five new House seats when he ran. At that pace, Indiana Democrats wouldn't seize a House majority in four election cycles. But Indiana Republicans have

presided with monolithic power in an era where the Hoosier middle class has been hammered, with per capita income declining 13% at a time when the GOP majorities have achieved a series of tax cuts for corporations, financial institutions, and wealthy farmers and ranchers. The Indiana middle class endured almost five years of a jobless rate over 8%, and saw their home values drop precipitously after generations of watching them consistently rise. Adult offspring are living with their parents, while Baby Boomers take care of their elderly parents, student debt now exceeds that of credit card holders, and Indiana's health metrics are consistently in the last national quintile. While the jobless rate under Gov. Mike Pence has descended below 7%, the job gains have been mostly at much lower wages than the bleeding of higher paying manufacturing jobs over the past six years. While the GOP controls 69 House seats, there is a sizable economic conservative faction in the lower Chamber that would be open to the kind of consensus Bayh was able to achieve in the 1990s when he forged a record excise tax cut, reformed the social safety net, and made education funding and attainment a top priority. Those fissures became evident during the constitutional marriage amendment debate last winter, with 23 House Republicans breaking against the controversial second sentence in that amendment. With the courts likely to decide that issue once and for all, the most divisive social issue in a generation will not likely be on the table in the next gubernatorial term. With Congressional approval at an anemic 14% and the Republican brand, according to a July CBS News poll, sagging to a historic low 28% (compared to 41% for Democrats), a case can be made that 2016 will offer Indiana Democrats a chance to make inroads into the emphatic GOP power that exists now. Democrats like John Gregg say Bayh is really angling for a potential cabinet post in a Hillary Clinton presidency, believing that Bayh will expend his efforts to help get his longtime friend and ally elected. But another side of that is a Bayh gubernatorial candidacy has the potential of pulling Indiana's 12 Electoral College votes into her column. Then there is the scenario of a Pence presidential (or vice presidential) nomination in 2016, creating an open seat. While Bayh is under considerable pressure to make a decision in early September, Pence is actually under a more arduous deadline if he is serious about a run for the national ticket in 2016. Will Bayh run? The conventional wisdom is "no." But Bayh has shocked us before, the last time in 2010, abruptly abandoning his U.S. Senate reelection bid at the 11th hour that only slickened Indiana Democrats' two-cycle descent into super minority status. In the minds of many Hoosier Democrats, while Bayh revived the Democratic Party a generation ago, he left it beached and dying in 2010, preceding a gutting of the party's power stanchions of education and labor. In his two terms as governor, the perception was that most policy initiatives came through the prism of a future presidential bid. Hoosier voters are watching Gov. Pence govern in similar style. Now that Bayh is back on his meds (as he puts it about his past presidential aspirations), the most intriguing question that may never be answered is how Evan Bayh would rule outside that realm if he did, indeed, decide to come back home again.

**INDY COUNCIL PANEL APPROVES 6-4 INCOME TAX HIKE FOR POLICE:** A City-County Council committee Wednesday recommended approving a slight income tax hike

to hire more Indianapolis police officers, but critics said it will still leave the department woefully short (Tuohy, *Indianapolis Star*). The Public Safety and Criminal Justice Committee voted 6-4 to send the plan to the full council for a vote. If approved, it would raise $29 million a year for police by increasing the local police income taxes about $64 a year for a resident earning $42,000 annually. But the measure would still leave the Indianapolis Metropolitan Police Department short of the officers it needs, Fraternal Order of Police Vice President Rick Snyder said. "This gets us a step closer, but it is only a baseline figure," Snyder told the committee members. Even so, he thanked the councilors for the "fortitude, leadership and political courage" to raise taxes. Under the plan, the IMPD would receive $16 million and use it to add 150 officers by the end of 2018. Other county law-enforcement agencies would share $11 million and $2 million would go to cites and towns in the county. But the measure falls short of the 270 added officers recommended by a police staffing task force, because it doesn't include Mayor Greg Ballard's proposed elimination of a local homestead credit to hire even more police. However, council Democrats oppose eliminating the tax credit. Ballard originally proposed funding new police with just the homestead credit savings, but Democrats have voted that plan down three times. Now, the mayor has proposed switching most of the homestead credit elimination savings over to a preschool program for poor children — with some funds still targeted for police. In exchange, he's supporting the police tax hike. Democrats, however, said they won't budge on their opposition to slashing the exemption, no matter what it is used for. And last week, the committee severed that proposal to slash the homestead credit from the proposed police tax increase. Ballard will now have to introduce that proposal to the full City Council at its next meeting Sept. 8, said Marc Lotter, a mayoral spokesman. If the council fails to approve the tax credit elimination, it would likely doom Ballard's plan to spend $25 million over five years to expand a pre-kindergarten program for underprivileged children. Republican committee members opposed separating the two tax measures because $2.5 million of the $7.5 million in savings from cutting the homestead credit could still be targeted toward police. "This was intended to be a package deal," said GOP Councilor Ben Hunter. "That $2.5 million could be used to add 20 officers (per year)." But Democrat Zach Adamson said the disagreement between the two parties about the homestead tax was so great they had to be torn apart. "It is two separate issues that have two separate degrees of support," Adamson said. "We need to keep them apart, so people can express those degrees of support." Republican Councilor Aaron Freeman said residents "should be frustrated" with the councilors because they are on their way to stopping short of fully funding more police. "We are never going to get enough police officers if we don't do both," he said of the mayor's proposals. Hunter said he feared the committee was paying for new officers piece by piece. "We're missing an opportunity to holistically approach a crime plan," he said.

**CIRCUIT BREAKER, TAX CAPS CONTINUE TO HIT LOCAL SCHOOL FUNDING:**As schools look to finalize their 2015 budgets within the next couple of months, one variable continuing to affect school finance is revenue lost to circuit breaker caps (Slagter,*Kokomo Tribune*). The current circuit breaker property tax cap,

which went into full effect in 2010, has cut anywhere from $47,000 to $7.95 million from area school corporations' budgets in the past five years, according to the Indiana Department of Local Government Finance. Each district is impacted differently, and even five years in, some still are struggling to compensate for the lost revenue. "It's a very large inequity," said Stanley Hall, director of finance and operations for Peru Community School Corp., which has lost out on $2.32 million since the circuit breaker went into effect. "The schools north and south of us have typically twice as much to spend per student on transportation." Schools rely on property taxes for their transportation, bus replacement, capital projects, debt service and pension debt funds. State money is distributed on a per-pupil basis to corporations' general funds, which cover salaries, classroom supplies and other expenses. The circuit breaker limits the amount people can pay on property taxes to 1 percent of the assessed value for homestead properties; 2 percent for residential properties, agricultural land and long-term care facilities; and 3 percent for nonresidential properties and personal property. All entities collecting property taxes from an area – which can include the county, city, townships, schools and libraries – must keep the total amount they levy within the circuit breaker cap. Schools in city limits are usually hit harder by the circuit breaker cap because there are more entities vying for the limited sum that can be levied. In Howard County, Kokomo School Corp. has lost the most revenue to the circuit breaker – $7.95 million in five years. Tipton Community School Corp. has been hardest hit in Tipton County, losing more than $660,000 in five years; by comparison, Tri-Central Community Schools missed out on just over $107,000 in the same period. Peru Schools has seen the most loss for school districts in Miami County. Operating with an average of $460,000 less annually since the circuit breaker was enacted, Peru's transportation fund took a 17 percent cut across the board, Hall said. The corporation now runs 12 bus routes instead of 17, and drivers make about $17 an hour instead of $22. Peru will not levy anything for its bus replacement fund in 2014 in an effort to leave more money for other funds. About $295,000 was taken from the general fund to maintain a minimal balance in the debt service fund. Reduced revenue due to the circuit breaker cap and declining enrollment has already led to staffing cutbacks, mostly through attrition, Hall said. On average, Kokomo Schools is operating with $1.6 million less a year because of the property tax caps. In 2014, the revenue loss jumped up to $3.03 million for Kokomo Schools, which is a 17.8 percent reduction from the full amount the corporation was certified to levy that year. "Kokomo Schools has reduced expenditures on construction-related projects paid for from our Capital Projects Fund," said Dave Barnes, director of communications for the corporation. Tipton Schools has not had to make any drastic cuts to adjust to the lower revenue, said Superintendent Kevin Emsweller. "Compared to some of the larger urban areas, it's been minimal," he said. "It's not a big impact for us."

**OBAMA WANTS NEW ISIS WAR PLAN BY END OF THE WEEK:** Leading U.S. officials now believe that America has to expand its air war against ISIS into Syria, but nobody knows yet how we can do it… or what will happen next (*The Daily Beast*). President Obama wants to decide by the end of the week whether or not his war in Iraq

against the Islamic State will expand to the group's haven in eastern Syria. But nearly everything about the potential military campaign is still in flux, administration officials tell The Daily Beast—from the goals of the effort to the intelligence needed to carry it out. ISIS's murder of American photojournalist James Foley and its continued military expansion have pushed the administration into an urgent drive to take action against the Islamic extremists in Syria. Despite the new urgency, the plans for such a strike are far from complete. In a series of high-level meetings Tuesday—including one gathering of the Principals' Committee, the administration's top national security officials—White House staffers and cabinet secretaries alike struggled to come up with answers to basic questions about the potential strikes. Among the unresolved issues: whether the U.S. has reliable intelligence on ISIS targets in Syria; what the objectives and limits of the strikes would be; and how the administration would defend the action legally, diplomatically, and politically. One huge unanswered question is whether the president will order the attacks, or whether he will ultimately balk, as he did this time last year after preparing for limited strikes against the Bashar al-Assad regime. One administration official working on Syria policy said the purpose of the meetings Tuesday was "to convince one man, Barack Obama," to follow through on the rhetoric and widen the aims of the war to include destroying ISIS in both Iraq and Syria. While Obama and his top officials have said they will need to address the threat of ISIS on both sides of the Iraq/Syria border, Obama has not said specifically what that means. Two administration officials tell The Daily Beast that the Pentagon and the U.S. intelligence community are developing options to widen the war to be considered by Obama's war cabinet this week. On Monday evening, The Wall Street Journal first reported—and The Daily Beast has confirmed—that the U.S. has flown surveillance aircraft into Syrian territory, part of the administration's rush to come up with intelligence that could be used in any strikes. Unlike in Iraq—where U.S. airstrikes are closely coordinated with Iraqi and Kurdish forces on the ground—the Obama administration has not yet consulted with ISIS's opponents in Syria about possible strikes…Obama  said this month that his new war against ISIS would include a counter-terrorism component as well. One former senior U.S. diplomat who has consulted with the administration on the ISIS threat told The Daily Beast that he would expect Obama to be presented with an option similar to Vice President Joe Biden's favored policy from 2010 for Afghanistan known then as counter-terrorism plus. This kind of approach would be a drone and air campaign against ISIS targets in Syria. The United States has conducted drone and airstrikes in Yemen, Pakistan, Iraq, Somalia, and Afghanistan. But in all of these cases the host government has requested them. This week, Syria's foreign minister warned the United States not to enter Syrian air space. Another factor Obama will have to consider if he does approve airstrikes in Syria will be whether he needs a congressional resolution to authorize a sustained air campaign. For the recent strikes in Iraq, Obama has relied on the inherent authorities in Article II of the Constitution, which asserts the president's role as commander in chief of the military.

**UKRAINE FEARS RUSSIAN INVASION ACCELERATING:** Fighting between the Ukrainian military and what Ukrainian and Western officials say are Russian troops

worsened early Thursday, prompting fears in Ukraine that a Russian invasion of their territory has begun (*Washington Post*). Ukrainian officials say Ukrainian troops are continuing to battle combined Russian and separatist forces on a new southern front around the border town of Novoazovsk, east of Crimea on the Sea of Azov. A military spokesman also said Russian troops are increasing surveillance from northern Crimea, the autonomous Ukrainian peninsula annexed by Moscow in March. As firefights and shelling continued all day Wednesday and into the night, there were differing reports on whether Novoazovsk, a previously quiet border town, had fallen to Russian-backed separatists. Russian troops and their allies do control villages north of there, according to military spokesman Andriy Lysenko. Referring to a "Russian-directed counteroffensive," State Department spokeswoman Jen Psaki said Wednesday, "Clearly, that is of deep concern to us, but we're also concerned by the Russian government's unwillingness to tell the truth, even as its soldiers are found 30 miles inside Ukraine." Widespread reports of Russian troop movements and fighting in Ukraine provoked renewed criticism from the North Atlantic Treaty Organization, whose secretary general said in an interview with British reporters Wednesday that it will deploy forces at new bases in eastern Europe for the first time in response to the Ukraine crisis and to deter Russian President Vladimir Putin, according to the Guardian newspaper. "We have reports from multiple sources showing quite a lively Russian involvement in destabilizing eastern Ukraine," Anders Fogh Rasmussen said. "We have seen artillery firing across the border and also inside Ukraine. We have seen a Russian military buildup along the border. Quite clearly, Russia is involved in destabilizing eastern Ukraine. . . . You see a sophisticated combination of traditional conventional warfare mixed up with information and primarily disinformation operations. It will take more than NATO to counter such hybrid warfare effectively." Moscow will consider the activity of NATO forces near Russia's borders in its own military planning, Russia's envoy to NATO told the Interfax news agency Thursday. "Obviously, we will take into consideration the configuration and activity of the NATO forces at the Russian borders in our military planning, and will take all that is necessary to reliably provide security and to ensure safety against any threats," envoy Alexander Grushko told Interfax. German leader Angela Merkel demanded an explanation from Putin for the Russian troop movements, the British Broadcasting Corp. reported. The conversation between the two leaders took place as fighting intensified, the BBC reported. Ukrainian President Petro Poroshenko said he has canceled his working visit to Turkey due to a "sharp aggravation" of the situation in the east, "as Russian troops were brought into Ukraine." Europe's security agency, the Organization for Security and Cooperation in Europe, has called an emergency meeting in Vienna on Ukraine, the BBC reported.

**STUDY FINDS MAJORITY THINK ECONOMY PERMANENTLY WORSE POST-RECESSION:** Americans fear the impact of the Great Recession is a permanent one, according to a new national study from Rutgers University (Strauss, *New Jersey Business*). The Work Trends report from the John J. Heldrich Center for Workforce Development said seven in 10 U.S. residents feel like the economy has undergone a permanent worsening, Rutgers said in a news release. That is up from 50 percent of

Americans in 2009, when the recession officially ended. The study, called "Unhappy, Worried and Pessimistic: Americans in the Aftermath of the Great Recession," also found that most Americans do not think the economy has improved in the past year, or will improve in the coming year. One in three thinks the economy has gotten better over the past year, while one-quarter thinks it will improve next year. That pessimistic outlook is based on experience, according to Carl Van Horn, director of the center and co-author of the report. Fully one-quarter of the public says there has been a major decline in their quality of life owing to the recession, and 42 percent say they have less in salary and savings than when the recession began," he said in a prepared statement. "Despite five years of recovery, sustained job growth and reductions in the number of unemployed workers, Americans are not convinced the economy is improving." Other key findings of the study included that only one out of six Americans think job opportunities for the next generation will be better than for their own; that contrasts with four in 10 in the 2009 study. Another negative finding is that about four in five Americans have little or no confidence that the U.S. government will make progress toward alleviating the nation's most important problems during the next year. Finally, the study grouped Americans into one of five categories, based on the impact the recession had on their lives: 16 percent were "devastated"; 19 percent were "downsized"; 10 percent were "set back"; 22 percent were "troubled"; and, 33 percent were "unscathed" "Looking at the aftermath of the recession, it is clear that the American landscape has been significantly rearranged," professor Cliff Zukin, co-author of the survey, said in a statement. "With the passage of time, the public has become convinced that they are at a new normal of a lower, poorer quality of life. The human cost is truly staggering." The survey of 1,153 Americans was conducted between July 24 and Aug. 3.

**HPI DAILY ANALYSIS:** Today's Daily Wire, like so many in the past year or so, carries stories from around the state of local governments scrambling to pay for simply basic public services. Indianapolis is hard pressed to pay for new police and programs to stem crime via at-risk youth efforts. Local schools, like Kokomo, have lost millions since the property tax caps. The town of Lake Station is paying for delayed road repairs with dwindling casino revenues. Towns and counties across the state are now losing a wave of talent and experience due to early retirements because state pensions are set to drop. A swath of counties might go without EMS services soon. Eventually we must come to grips with the systemic funding crisis and other challenges facing local units of government. *–Matthew Butler*

Campaign

**2014: OUTSIDE GROUPS READYING FOR 'PIVOTAL' IPS SCHOOL BOARD ELECTIONS -** Outside groups that are aiming to influence how Indianapolis Public Schools is run are gearing up to push for candidates who best fit their philosophies to be elected from among a crowded field seeking three seats this fall (Colombo and Elliott,*Chalkbeat Indiana*). That could prompt the district's teachers union, which has

been skeptical of some ideas to change IPS, to break recent tradition and endorse candidates in the race, a union official said. The stakes are high for a board that, since 2012, has leaned more in favor of reform ideas like giving schools more autonomy and forging partnerships with charter schools. Two of the more stringent skeptics on the board — Michael Brown and Samantha Adair-White — face opponents who are more in line with the board's majority on those issues. "This is a pivotal point in IPS' history," said Indianapolis Chamber of Commerce vice president Mark Fisher. "There's a real chance to change the trajectory of the district. It's a positive thing that we have so many candidates running." The Indianapolis Chamber, which has in the past criticized the district for being inefficient with spending its money, has already endorsed former Democratic state Rep. Mary Ann Sullivan, ex-school board member Kelly Bentley and LaNier Echols, a charter school dean, from among 10 candidates. All three support accountability-based school reform ideas. Sullivan and three others are challenging IPS school board President Annie Roof. Bentley and fellow challenger James Turner are taking on incumbent Adair-White, and Echols will run against Brown, the longest serving board member. Fisher said the chamber has long thought the board needed people on it with stronger management skills, but that was made more clear this year when new Superintendent Lewis Ferebee announced the district didno actually have a $30 million deficit in 2013 as projected by former superintendent Eugene White. In fact, IPS had a $8 million surplus and Ferbeee said it appeared the extra money had been intentionally obscured by inflated budgets in the past. "For IPS to fix its academics, it can't constantly be putting out operational fires," Fisher said. "Our leadership felt strongly we needed new representation so we went through the process of identifying, vetting and endorsing three candidates." For instance, he said, Bentley was an early leader at IPS in calling for more transparency in governance on the school board. She often got into arguments with White, such as when he refused to turn over documents related to the district's budget. Sullivan, who formerly worked for the chamber and serves on its council for education, has a "proven record at the Statehouse," Fisher said, supporting ideas like school choice and test-based accountability. Sullivan was often the lone Democrat supporting school reform bills, such as those to expand charter schools and toughen teacher evaluation rules. She left her seat in the House in 2012 for an unsuccessful run at the state Senate. The chamber became interested in Echols, Fisher said, because of her experience teaching at two IPS schools through Teach for America and her experience as an administrator for the charter school Carpe Diem. "We understand where people might feel like she might just be for charters, but she's proven to us she wants to strengthen the traditional school system in Indianapolis," Fisher said. Four years ago, the board slowly began to move toward change with the surprise election of Roof and Adair-White. Both were critical of many of the White's policies, but he maintained a solid four-member majority, including Brown, who consistently supported him. Most of the complaints of Roof, Adair-White and board member Diane Arnold were ignored. But in 2012, three new board members were elected — Caitlin Hannon, Sam Odle and Gayle Cosby. All of them campaigned in favor of changing the district and within a week of taking office they ousted White, who agreed to a buy out. Since then, board alliances have shifted and remain unsteady.

Hannon, Arnold and Odle are the strongest advocates for most reforms, usually joined by Roof. Brown and Adair-White have often been aligned in asking skeptical questions and sometimes voting against changes the majority supports. Cosby has confounded some of the reform groups who supported her in 2012 by sometimes supporting the majority and sometimes joining the skeptics.

**2014: IPS SCHOOL BOARD RACES DRAWING BIG OUTSIDE DOLLARS -** Stand for Children, a school reform organization that advocates for change within IPS and supported Hannon, Odle, Arnold and Cosby in 2012, said its advocacy arm also plans to make its endorsements soon (Colombo and Elliott, *Chalkbeat Indiana*). Spokeswoman Kate Shepherd said the organization is working to contact candidates and ask them about their positions on various issues. A committee will then decide the endorsements. IPS's teachers union typically doesn't make official candidate endorsements, said Ann Wilkins, an Indiana State Teacher's Association director who advocates for IPS. But that could change for this race. Wilkins said she remembered a time when school board races drew candidates who would raise anywhere from $2,000 to $5,000 to support their candidates. But in the 2012 IPS school board race, candidates raised as much as $65,000, sometimes from organizations with no official ties to the community. For example, board member Caitlin Hannon a received $10,000 donation from people including from former New York Mayor Michael Bloomberg. "If you're a grassroots person, you can't afford to compete against that," Wilkins said. "It's just different now. The teachers union doesn't have money to help a campaign like that. If we say we're going to endorse someone, we'll get out and do phone banks."

**2014: GOP CREATES VIDEO GAME TO CONNECT WITH YOUTH VOTE -** Republican campaign strategists are taking political gamesmanship quite literally – releasing an online game that involves stomping out Democratic foes while attracting a cadre of GOP recruits (Strauss, *Scripps Media*). Dubbed "Mission Majority," the video game is sponsored by the National Republican Senatorial Committee. Mission Majority" stars a diminutive cartoon elephant named Giopi, presumably a distant cousin of the iconic Mario who pioneered the computer game form in the 1980s and 1990s. Adorned in red, white and blue, Giopi says he is here "to show you how we can win back the Senate!" Perhaps revealing the GOP's 2014 campaign strategy, gamers smash Democratic agents as they reach for golden keys "to unlock the Senate and help Republicans win the Majority this fall." Each key represents new Republican volunteers. Collect three golden keys and you are on the way to the game's next level (with an intermediate link to a site "where you can support Republicans in real life"). At Level 1, the first encounter is with "Taxer," a frazzled figure sent, the game explains, by President Obama and Harry Reid to deliver "job-destroying" taxes. Above a hilly terrain, three golden keys beckon. We failed miserably at "Mission Majority." Despite several attempts, we were unable to collect the golden keys leading to the next level. But surely younger users, whom Republican strategists seek to attract, would have little trouble navigating these digital obstacles. The payoff for the GOP comes before the game even begins. To play "Mission Majority," you have to first provide an email

address or access to your Google or Facebook account. "This is all about getting the info of what they hope will be young people who click on the link and could potentially vote for Republicans down the line and/or volunteer, donate, etc.," writes political blogger Jaime Fuller in the Washington Post's "The Fix."

Congress

**LEAKED RECORDING OF MCCONNELL VOWING TO BLOCK MINIMUM WAGE HIKE:** U.S. Senate Minority Leader Mitch McConnell told a conference of rich, politically active conservatives in June that he wouldn't allow votes on the minimum wage and extending unemployment if he becomes majority leader, according to a leaked audio recording (Gerth, *Louisville Courier-Journal*). In the recording, which appeared on the website of *The Nation,* he also said that passage of the McCain-Feingold Act to limit political contributions was "the worst day of my political life." The Kentucky Republican's campaign didn't deny the recording was accurate and, in fact, said it shows that he is "committed to fighting President Obama's liberal, anti-coal agenda." The event was organized by billionaire brothers Charles and David Koch, who donate heavily to conservative and tea party causes. The Nation reported that political action committees and people with ties to Koch Industries have contributed at least $41,800 to McConnell during this campaign cycle. The recording includes passages in which McConnell says he would block votes on issues like raising the minimum wage, extending unemployment benefits and refinancing student loan debt. "We're not going to be debating all of these gosh darn proposals," he said during the discussion. "These people believe in all the wrong things." Moments earlier, McConnell had criticized Democrats for favoring campaign finance law, saying "they are frightened of their critics. They don't want to join the tradition in open discourse." The senator is engaged in a closely contested Senate race against Democrat Alison Lundergan Grimes, and her campaign seized on the recording as proof he is out of touch with Kentuckians.

**MCCONNELL SAID MCCAIN-FEINGOLD 'WORST DAY OF HIS POLITICAL LIFE':**Throughout his speech to the group, McConnell criticized "liberal" attempts to pass legislation over the years that would limit the influence of money on politics (Gerth,*Louisville Courier-Journal*). He also attacked passage of the campaign finance bill penned by Republican Sen. John McCain and Democratic Sen. Russ Feingold, which sought to cut down on "soft money" given to political parties and limited "issue ads" by outside groups in the days leading up to the election. "The worst day of my political life was when President George W. Bush signed McCain-Feingold into law in the early part of the first administration," McConnell told the group. Jonathan Hurst, Grimes' campaign manager, said such a statement is "outrageous." "There have been many bad days this country has had over the last 30 years and he's saying that's the worst day of his career," Hurst said, noting that during McConnell's tenure, the entire economy almost collapsed in 2008, there have been "bad days in wars" and that McConnell has undoubtedly received reports about job losses in Kentucky. "It's breathtaking that he would say this is the worst day of his career," Hurst said.

**BROOKS TO HOST MENTAL HEALTH LISTENING SESSION:** U.S. Rep. Susan W. Brooks will co-host a listening session on mental health with the Indiana Council of Community Mental Health Centers, Mental Health America of Indiana and the Indiana Psychiatric Society on August 28 at Aspire Indiana in Carmel from 9:30 – 11 a.m. (*Howey Politics Indiana*). The listening session will focus on H.R. 3717, the Helping Families In Mental Health Crisis Act, sponsored by Representative Tim Murphy and cosponsored by Congresswoman Brooks. Participants from the mental health community will discuss with the Congresswoman how the federal government can streamline its programs and services to truly address the needs of the mentally ill and their families.

General Assembly

**WORK-SHARE PROGRAM DEBATED BY STUDY COMMITTEE:** Business leaders split Wednesday on their support of a proposed work-share program that would let Indiana companies reduce work hours for employees, who could then collect partial unemployment benefits (*Statehouse File*). The program – which is authorized by the federal government and has been implemented in 29 states – is designed to help both companies and their workers better weather economic downturns. Mike Ripley, vice president for health care policy at the Indiana Chamber of Commerce, told a legislative study committee that the program gives companies another tool to avoid mass layoffs when times are tight or production is low. And he said workers win by maintaining their benefits and most of their salaries. "It's better to have people working than not working," Ripley said. But Ed Roberts, vice president of the Indiana Manufacturers Association, said he's concerned the program could put more stress on the state's unemployment system, which already is in debt to the federal government. Indiana still owes more than $800 million that it borrowed during the last downturn when the taxes companies paid into the unemployment trust fund couldn't cover the payments to laid-off workers. Roberts said the state should be "extremely cautious" about any program that might affect the solvency of the state's trust fund. He said the work-share program "is fraught with the potential for starting up an engine and letting parts fly off and maim the innocent bystander." Officials at the agency that would oversee work share are skeptical as well. Josh Richardson, a deputy commissioner at the Indiana Department of Workforce Development, said there are "real concerns" about the costs of expanding eligibility for unemployment. "Do we really want to make it cheaper or easier to reduce people's work hours?" Richardson asked the Employment and Labor Study Committee. "That could result in additional reductions and that harms the trust fund." But Chamber of Commerce officials said work share shouldn't hurt the unemployment fund – particularly because a company's alternative option is laying off its workers, which would drain more money from its coffers. The federal government authorized work share programs about three decades ago but interest in the option ramped up in 2012, when Congress made $100 million in grants available to states to encourage participation. Indiana hasn't been able to take advantage of any of that money, and Democrats – who are the minority party in the Indiana House and Senate –

have been clamoring for the General Assembly to take up the issue. Now, lawmakers in both parties seem at least somewhat interested. Study Committee Chairman David Ober, R-Albion, said a work-share program could actually help the unemployment fund in an economic downturn. "If we implement the program, there is a chance we can minimize some of the employment job loss in the state," he said. That's because people might otherwise lose their jobs and end up on long-term unemployment. Work share is meant to provide temporary relief – and pay only a partial benefit. Tom Easterday, executive vice president of Subaru of Indiana, told the committee that a work-share program could also help the state retain skilled workers. Too often, he said, workers take jobs out of state after a layoff and might never return to Indiana. Then, when companies are ready to ramp production back up, they spend years training new workers to do the jobs. Easterday, who is chairman of the Indiana Automotive Council, said work-share would allow those workers to retain most of their salaries and maintain a connection to a company. It would also give companies more consistency in their workforces and allow them to increase production more quickly. "To retain those skills is very important for the state of Indiana," he said. But Richardson said it's not a problem that skilled workers find other jobs after a layoff. He said overall wages rise when workers are able to gain skills and then take them to another position and the state shouldn't step in to prevent those moves. "That's the economy at work," Richardson said. "That's what is supposed to happen."

State

**GOVERNOR: NGA TAPS INDIANA FOR POLICY ACADEMY -** The National Governor's Association Center for Best Practices recently announced the selection of Indiana as one of 14 states to participate in its policy academy aimed at aligning education and workforce training systems to meet state's economic needs (Kelly, *Fort Wayne Journal Gazette*). As a designated recipient, Indiana will receive grants and opportunities from the NGA to further learn from state colleagues and national experts, as well as technical assistance from the NGA Center for Best Practices. "We were the first state in the country to create a specific agency to jointly coordinate our education and workforce efforts a year ago, and the interest from other states has been high in understanding our models and initial work plans," said Gov. Mike Pence.

**GOVERNOR: PENCE, WALORSKI REDEDICATE HIGHWAY TO MANGUS –** Wednesday, Governor Mike Pence joined U.S. Rep. Jackie Walorski, the U.S. 31 Coalition and other community members to celebrate and officially open 20 miles of new U.S. 31 freeway between Plymouth and South Bend (*Howey Politics Indiana*). "Indiana is finishing what we started by upgrading three congested sections of U.S. 31 between Indianapolis and South Bend," Governor Pence said. "The new U.S. 31 in Marshall and St. Joseph counties will provide a safer, smoother ride as drivers hit our highways for fall festivals and football games." During the ceremony, Governor Pence dedicated a portion of U.S. 31 near Lakeville as the "Richard W. Mangus Memorial Highway." Mangus, a native and life-long resident of Lakeville, was elected to the

Indiana House of Representatives in 1972 and served with distinction until 2004. Mangus was an early supporter of the new U.S. 31 route through the area and passed away before the project broke ground in 2008. The new U.S. 31 is 20 miles of divided, four-lane highway between the U.S. 20 Bypass in South Bend and U.S. 30 near Plymouth.

**STATEHOUSE: ZOELLER CONTINUES ACTION AGAINST LAFAYETTE TRASH COMPANY -** Indiana Attorney General Greg Zoeller is still fighting for customers who were affected by a Tippecanoe trash company. Zoeller has filed a second complaint against Tippecanoe Waste Removal, Inc., but this time in bankruptcy court (Kruczek, *WLFI-TV*). Zoeller is making additional efforts to regain restitution for customers who paid for trash-collection service, but didn't receive it from TWR. He is requesting the company's debts owed to consumers not be discharged by the bankruptcy court, at which time Zoeller will continue to pursue the monies owed to customers effected through the Tippecanoe County Superior Court. In January, the initial lawsuit was filed against the former Lafayette-based business for failing to collect trash after taking customers' advance payments. In May, the owners of TWR, Kurt and Melissa Kanable, filed for bankruptcy protection and listed all consumer debts in their filings. "The owners of Tippecanoe Waste Removal deliberately deceived consumers, taking payments for trash removal while knowing full well the services would not be provided," Zoeller told News 18 in a release. "This type of deceptive business practice cannot go unpunished, and my office is committed to making every effort to ensure that this money is paid back to Tippecanoe community members who were wrongfully charged."

**EDUCATION: ISTA URGES PENCE TO SEEK ACCOUNTABILITY DELAY -**Indiana's largest teachers union is urging Gov. Mike Pence to support freezing the state's education accountability system for one year because of revisions to the ISTEP test being driven by the state's new academic standards (*Associated Press*). Indiana State Teachers Association President Teresa Meredith asked Pence in a Tuesday letter "to take the lead to follow common sense" and support a one-year moratorium of the state's system that evaluates schools' and teachers' under the high-stakes test. The retooled ISTEP standardized test will be administered next spring and will assess students' mastery of the state's newly adopted math and English benchmarks that changed after Indiana became the first state to pull out of the national Common Core curriculum standards. Meredith said that because students' scores are expected to be lower than normal on the revised test, it would not be fair to use those in determining performance. ISTEP test scores are used in calculating teacher pay and school funding, as well as school grades under the state's "A-F" system. "Labeling a school A-F and evaluating teachers based on the initial year's baseline score would be unfair; not to mention what test results will do to the students who don't score well," Meredith said in her letter to Pence. She added that Education Secretary Arne Duncan's announcement last week that states can apply for extra time before using student test scores to judge teachers' performance gives Indiana "newfound 'permission'" to follow that course.

Daniel Altman, a spokesman for state Superintendent of Public Instruction Glenda Ritz, said Ritz is concerned about "the viability" of the test score data from the upcoming ISTEP test. But he said the state Legislature has the final say on whether Indiana pauses its accountability system. "In order for accountability to work, it has to be both fair and accurate," Altman said in a statement, adding that "it is worth noting that individuals as varied as Secretary Duncan and Bill Gates have recommended that we take time to look at this data before we use it for high stakes evaluations." Indiana lawmakers pulled the state out of Common Core standards earlier this year, leading the State Board of Education to adopt new school academic standards in April. Federal education officials have said that the revised ISTEP test will have to be given next year in order for the state to maintain its waiver from the No Child Left Behind law. The test's current revision will be the third time it's been revamped since 2009. Pence said in a June letter to Duncan that he opposes pausing the state's education accountability system. He said in that letter that delivering school grades and evaluating teachers is "essential to ensuring that every child has access to a quality school," that teachers are rewarded for excellence and strategies are devised to improve underperforming schools. Pence spokeswoman Kara Brooks said Wednesday in a statement that the state's accountability system is driven by the state Legislature and decisions made by the State Board of Education, which she said has not had time to "consider all the elements and options."

**EDUCATION: SPIKE IN CHARTER SCHOOL'S SCORES LED TO INQUIRY, CLOSURE -** The numbers are staggering. Or so state investigators with the Department of Education thought when they were tipped off by Mayor Greg Ballard's administration that something might be awry at Flanner House Elementary, sources tell I-Team 8 (Haeberle, *WISH-TV*). I-Team 8 obtained documents indicating just how much of a dramatic increase unfolded year to year at the now embattled charter school. The data – confirmed by state officials – was printed in the annual school performance results published by IDOE. In 2012, the number of fifth grade students at Flanner House Elementary passing the language arts portion of the ISTEP+ exam was just over 54 percent. A year later, it was 100. In that same time frame, the number of sixth grade students passing the language arts portion was just below 43 percent. A year later, it was 100 percent. Math scores also spiked from 2012 to 2013. Eighty-three percent of fifth grade students at Flanner House passed the math portion in 2012. A year later, it was 100. In the 2012 school year, 61 percent of third graders passed the math portion. A year later, that number rose to almost 97 percent. In the same period, fourth grade math scores rose from 71 percent passing to more than 94 percent. Those scores, coupled with an increase in eraser marks and "perfectly" filled in bubbles from wrong to right answers indicated to investigators "strong evidence" of cheating, the source told I-team 8. The school is set to close September 11, which has left many parents and students with mixed emotions.

**EDUCATION: NOTRE DAME POVERTY INITIATIVE RECEIVES $15M -** A $15 million donation will boost a poverty research initiative at the University of Notre Dame

(*Inside Indiana Business*). The gift from the Wilson Sheehan Foundation will support the Lab for Economic Opportunities, which focuses on issues including early childhood development, job readiness and homelessness prevention.

**MILITARY: INDIANA NATIONAL GUARD UNIT RETURNS FROM KUWAIT -** Tearful reunions marked the return of 10 National Guard soldiers to their Indiana home on Wednesday (*WRTV-TV*). Soldiers from Company F, Air Traffic Support, returned to Indianapolis from their deployment in Kuwait. Dozens of family and friends waited anxiously for them to arrive. Watch our video to see the reunions firsthand and hear from the soldiers. All of those who returned were part of Operation Enduring Freedom and were first deployed last December.

**ENVIRONMENT: DNR RECEIVES GRANT TO FIGHT BAT DISEASE -** Indiana will receive $36,500 from the federal government in hopes of curbing the spread of white-nose syndrome, a fungus that can be fatal to many bats (*Associated Press*). Indiana is one of 30 states receiving a total of nearly $1.3 million in grants to combat the disease. Eight Midwestern states, including Indiana, will split $280,000. The money will be administered through the Department of Natural Resources to support research on the disease, to detect and respond to it, and to monitor bat populations. The grants are awarded by the U.S. Fish and Wildlife Service. Officials say white-nose syndrome has spread from one state in 2007 to 25 states and five Canadian provinces this year.

Nation

**WHITE HOUSE: OBAMA PURSUING CLIMATE ACCORD, NOT TREATY -** The Obama administration is working to forge a sweeping international climate change agreement to compel nations to cut their planet-warming fossil fuel emissions, but without ratification from Congress (*New York Times*). In preparation for this agreement, to be signed at a United Nations summit meeting in 2015 in Paris, the negotiators are meeting with diplomats from other countries to broker a deal to commit some of the world's largest economies to enact laws to reduce their carbon pollution. But under the Constitution, a president may enter into a legally binding treaty only if it is approved by a two-thirds majority of the Senate. To sidestep that requirement, President Obama's climate negotiators are devising what they call a "politically binding" deal that would "name and shame" countries into cutting their emissions. The deal is likely to face strong objections from Republicans on Capitol Hill and from poor countries around the world, but negotiators say it may be the only realistic path.

**ENERGY: GAS PRICES JUMPING AGAIN -** You may have noticed that gas prices jumped up again, or they will soon if they haven't at your station (Steele, *WIBC*). One gas price watcher says that's normal, not just for Indiana, but also for other Midwestern states. "Prices started jumping to about 3.59 a gallon around central Indiana. We saw a hike last week just like now, but last week it only went to 3.55," said Patrick DeHaan, senior petroleum analyst with GasBuddy.com. The price for self-serve regular unleaded

had fallen as low as 3.19 a gallon at some stations this week. The jump in prices has nothing to do with the price of oil, which is around a relatively low $93 per barrel. Rather, this is the beginning of another price cycle. "Price cycling is the term coined by the Federal Trade Commission," DeHaan said of the practice that is common in Indiana, as well as Ohio and Michigan. "This is the 24th time this year that we have seen these big price hikes, and of course this will do nothing to dispel the myth that gas prices go up for the holidays, because everyone will think that's why it is going up," DeHaan said. Price cycling, DeHaan says, is simply the way gas stations in the Great Lakes region compete with each other for customers. "Markets are so competitive, Indianapolis, Fort Wayne, South Bend, every city in Michigan - it's really just stations engaging in a year-round price war," DeHaan said. Stations allow prices to fall as far as they can while still making some profit, even if it is only a penny or two-per gallon, then they will raise prices anywhere from 20-to-40 cents a gallon to recoup some revenue before allowing the price to trickle back down. DeHaan says it's even possible prices could start declining during Labor Day weekend, when most everyone thinks they will stay high. There have been studies, DeHaan says, that show consumers actually come out ahead in states like Indiana where gas stations cycle prices. "Because it gives you the opportunity to fill up when stations aren't making any money. No other states do that. Stations outside the Great Lakes are always making about 10-to-15 cents a gallon of profit every day."

**AGRICULTURE: FARM INCOME FALLING FROM RECORD 2013 LEVELS -** Lower prices for corn and soybeans will drive the profits of U.S. farmers down to an estimated $113.2 billion in 2014, a decline of 14 percent from last year's record, according to the Department of Agriculture (*Bloomberg News*). The forecast for this year's income is up 18 percent from a February estimate as livestock revenues may reach an all-time high, the USDA said in a report on its website. Gains in farmland values that climbed 8.1 percent this year are slowing. While rising hog and cattle prices have aided livestock producers, record grain and oilseed harvests are dragging profits, said University of Missouri at Columbia agriculture economist Pat Westhoff…Income from crops will be up 6.1 percent from the February forecast, to an estimated $200.9 billion, while livestock will rise 14 percent to $209.6 billion. The outlooks were raised because of "more optimistic price expectations" this year for both crops and livestock than the February forecast, the USDA said in its report. Soybean futures in Chicago have slumped 21 percent in 2014, while corn fell 14 percent. Hog futures climbed 11 percent, and cattle prices are up 10 percent. Expenses for this year including seed, fertilizer and animal feed will be $368.4 billion, up 5.8 percent from the February forecast and 4 percent from 2013.

Local

**CITIES: EXPLOSION, FIRE AT WHITING'S BP REFINERY -** Fire broke out about 9 p.m. Wednesday after an explosion at the BP refinery in Whiting, Indiana, fire officials said (Quinn, *Post-Tribune*). BP America spokesman Scott Dean confirmed in a news

release early Thursday that the Whiting refinery experienced "an operational incident" on a process unit on the refinery's north end. Its in-house fire department responded, and the fire was extinguished by 10:55 p.m. "Refinery operations were minimally impacted as a result of the incident, and the refinery continues to produce products for customers," Dean said. One refinery employee was taken to a local hospital as a precaution but was later released, Dean said. Two neighbors said via social media that they heard or felt the blast about 9 p.m. The blast was heard as far away as Highland and Griffith.

**CITIES: MIXED REVIEWS AT INDY VA CENTER TOWN HALL -** A town hall meeting at Roudebush VA Medical Center was filled with about 30 veterans to share their experience with the hospital (*WISH-TV*). The meetings are required and a directive of the new VA secretary in the midst of the scandal. The hospital talked the first half hour about awards and accomplishments. Contrary to what most veterans have told the I-Team 8 over the years, most comments were positive. However, not all of them were as positive. "I'm going to be quite frank and to the point. This hospital saved my life," said veteran Kent Morgan. "I do hear negativity on the news and I have not experienced that," said another veteran attending the meeting. David J. Lindauer/Ret. USMC said there are great people who work at the VA, but there is a lot of people who can be rude and obnoxious. "Your physicians, your staff did it. I didn't do it on my own. In this command situation you would have been relieved. It's unset, unprofessional. You have rude personnel here. It needs to be dealt with. And if you're not getting the information you need to relieve the staff under you you're not fixing the problem," said Lindauer. Many of the veterans questioned why they were not notified of the meeting and said many found out from stories the last two days on 24-Hour News 8. Roudebush is one of the VA Medical facilities inspected in May and red flagged for another review by the Inspector General. Secret waiting lists have been uncovered at VA facilities around the country and Roudebush's union president says wait times were manipulated.

**CITIES: CUSTOMER SERVICE FIRM TO HIRE 1,000 IN INDY -** Interactions Corp. plans to add 1,000 new employees to its local workforce by 2015, focusing mainly on customer service and data entry functions (King, *Indianapolis Business Journal*). Based in Boston, Interactions provides automated systems for customer care with a conversational tone. The systems are run from so-called "iCenters," the largest of which is in Indianapolis at 2525 Shadeland Ave. Called "intent analysts," the 1,000 new full-time and part-time employees will work at that facility, said Dan Fox, a marketing manager for Interactions Corp. The iCenter currently employs several hundred workers, Fox said. The new jobs will pay within a range of $12 to $18 per hour, Fox said, based on the productivity, speed and accuracy of the individual employee.

**CITIES: INDY'S EAST SIDE TO RECEIVE $1M BOYS AND GIRLS CLUB -** Community leaders broke ground Wednesday on a new Boys and Girls Club in an area of Indianapolis plagued by high crime and poverty rates (Trent, *WXIN-TV*). Located at

38th Street and Post Road, the facility will serve about 1,000 families on the city's far eastside, where poverty levels are twice as high as other areas in Marion County and nearly four out of ten residents are under the age of 18. Statistics show 69 percent of those children are growing up in single parent homes and 87 percent qualify for free or reduced school lunches. The new facility will be located next to the Community Alliance of the Far Eastside, or CAFE. The Boys and Girls Club will partner with CAFE to provide services to children ages five through 18. Pastor James Jackson, a CAFE board member, says together the two organizations can make a huge difference. "There's a lot of poverty. This area is a federally mandated food desert. There's a lot of hurt and a lot of pain out here," says Jackson. "So for something like this to come along, it brings a lot of hope and also expresses a lot of love for the people who live in this area." Jackson says the new Boys and Girls Club will keep at risk children off the streets. "A lot of juvenile crime takes place after school lets out," he says. "The Boys and Girls Club is going to be very instrumental in helping to make sure when young people get out of school they have a wonderful place to come, not only for recreational activities, but also for nutritional meals." The new 22,000 square foot facility will be named "Finish Line Boys and Girls Club" in honor of a $1.25M donation from The Finish Line, Inc. and The Finish Line Youth Foundation.

**CITIES: EVANSVILLE TO RECEIVE $500K EPA BROWNFIELD GRANT -** The city of Evansville has been awarded $500,000 to boost cleanup efforts at the former Swanson-Nunn Electric Co. site (*Inside Indiana Business*). The property is near the future Indiana University School of Medicine campus and has already undergone several significant remediation initiatives.

**CITIES: WEST LAFAYETTE CONSIDERING PARKS MASTER PLAN -** The city of West Lafayette has nearly doubled in size, and that means changes could be coming to the city's parks and recreation system (Campbell, *WLFI-TV*). "We need to do a new master plan for parks and recreation particularly since we added all of this huge area," Superintendent Joe Payne said. With more land in the city of West Lafayette after the recent annexation comes more opportunities. "The presumption is that if you a green space you can put up a swing in there or a bench in there or some playground equipment and you can have a park, but it's unfortunately not quite that simple," Mayor John Dennis said. Dennis said just like any other aspect of the city, a master plan has to be carefully thought out. He said the city will work closely with Purdue and neighbors near the newly annexed parts of the city. On top of expanding existing trails, Payne told News 18 last week that residents want more green space. "The open space we have is high premium," Payne said. "There are more folks wanting to use the open space in Cumberland Park, another park we got to create from an old pasture, and there are possibilities somewhere out there near that 231 corridor." Dennis said unique ideas are also welcome. "I'd like to see some creativity. We've had conversations about the possibility of another water feature somewhere within the city. The possibility of having another rec center somewhere within the city. I'd like to explore those options as well," Dennis said. Before work begins on the master plan, the city needs to find a new parks

and recreation superintendent. Payne is retiring this week. Dennis said the city will launch a nationwide search for a new superintendent. One of the main questions during the interview process will be what ideas they for the new master plan they'll be responsible for putting together. "What parks will be done, how we can utilize our trail network to support our parks system and, probably most importantly, to make sure that we can have the proper type of facilities that would engage the new component of our population base — the student population," the Mayor said.

**CITIES: GM TO INVEST $48M IN BEDFORD PLANT -** General Motors plans to invest $48.4 million in its Bedford powertrain castings plant (Kuhn, *Indiana Public Media*). The investment will go to support GM's new Ecotec engine components. The Bedford plant will produce transmission casings, converter housings and small gas engine blocks. The new engines are designed to support hybrids and alternative fuels. This comes in addition to the over $300 million already invested to the Bedford plant in the last five years. The Bedford plant employs more than 600 workers.

**CITIES: VALPO STREETS, BRIDGE NEED $400K IN EMERGENCY REPAIRS -** Two roads on the city's west side remain washed out after Friday's flash floods, and one includes a bridge that will take time and money to replace, city officials said Monday night (Wolf, *Post-Tribune*). The areas closed are the south side of Vale Park Road, just west of Froberg Road, and the Harrison Boulevard bridge over Beauty Creek. The bridge is just west of St. Paul Catholic Church and Old Oak Drive. City engineer Tim Burkman told the city council on Monday that city crews will start repairing the Vale Park section on Tuesday, and it should be completed by week's end. However, the bridge could cost $300,000 to $400,000 to replace, and officials haven't decided where the money will come from. Burkman said his department is considering ordering a pre-cast bridge, but building one will probably be faster. He said he will have cost estimates by the Sept. 8 council meeting but gave no start date for the project.

**CITIES: LAKE STATION USING CASINO REVENUE TO PAY BILLS -** The City Council approved a request from Mayor Keith Soderquist last week to pour $420,000 of casino revenue into the flagging general fund, but at least one councilman cried foul (Gonzalez, *Post-Tribune*). Councilman Don Huddleston (2nd Dist.) said the mayor sprang the decision on the council without advanced discussion. He also said the city should have been using the money to fix roads and sewage problems all along. "I have roads in my district that need to be paved," Huddleston said. "How did our budget get so bad in the red? We've got sewage running out into people's yards every time it rains. That money should never have been accumulated in the first place." The city gets about $125,000 a year in casino tax revenues, about a third of what it used to get, and keeps it in a fund for road and infrastructure improvements Soderquist said. The city spent only some of the fund over the past five years, accumulating the money the council moved into the general fund, which is often in the red here. Like all taxing districts, Lake Station has had to adjust to far less revenue due to permanent property tax caps added as an amendment to the state constitution in 2010. At $4.2 million, the general

fund, including $2.3 million for public safety, had to be shored up, and cutting money from the police and fire departments to save money was not an option, Soderquist said. "When you tally all of the funds, you have the total amount in (the city's) checkbook," he said. "If the money's not there, overall, to spend we don't spend it. We definitely have paved the streets and worked on the infrastructure, but not all of it. (The casino fund has) accumulated extra funds."

**COUNTIES: VIGO SPECIAL DEPUTIES UNDER INVESTIGATION -** Indiana State Police are investigating as many as four special deputies with the Vigo County Sheriff's Office (Brown, *WIBC*). The non-payroll special deputies were performing traffic control at the Vigo County Fairgrounds on August 23. The deputies allegedly issued citations for various offenses to drivers and then told the drivers they could make a cash payment in lieu of the citations being submitted to the court. Some of the victims reportedly took the cash option and reported the deputies' alleged actions to law enforcement. State Police say the special deputies were reportedly wearing tan deputy sheriff t-shirts, driving their personal vehicles with sheriff signs attached to the exterior and utilizing red and blue police lights. State Police say the alleged acts were not endorsed by Vigo County Sheriff Greg Ewing and did not involve any full-time payroll deputies. The investigation is expected to take three to four weeks before a report is submitted to the Vigo County Prosecutor's Office.

**COUNTIES: TIPPECANOE TO LOSE OVER 300 YEARS EXPERIENCE TO RETIREMENTS -** The numbers are large. By the end of the week more than 50 years of experience in West Lafayette, 100 years in Lafayette and 170 years in Tippecanoe County offices will be gone. More public employees are choosing now to retire (Roberts, *WLFI-TV*). "I think most of them were fueled by the change," Tippecanoe County Commissioner John Knochel said. "That was their primary reason for leaving because of those changes in the annuity," Lafayette Mayor (D) Tony Roswarski said. Those changes Roswarski and Knochel are talking about deal with the Indiana Public Employees' Retirement Fund annuity rate. As News 18 previously reported, on October 1 the rate will go from 7.5 percent to 5.75 percent. To keep the 7.5 percent you have to retire by September 1. That's Monday. Knochel said nearly ten people retire by the end of the week. Two offices will take a big hit. "The prosecutor's office is losing better than 60 years of experience, and the parks department is losing better than 65 years," Knochel said. Last week we reported West Lafayette lost two department heads because of the change. In Lafayette, no department heads are leaving, but four other workers are retiring. "That institutional knowledge when you think of all the changes that have taken place over the last, for some of these guys, 30 years there has been a lot of changes, and they've been able to make those changes, but still have the historical perspective that helps you not make mistakes," Roswarski said. Mayor Roswarski and Commissioner Knochel said salaries are competitive with the private sector, but often times are less. However, they said the job security in the public sector and the upward mobility in offices are helping them fill the open spots.

**COUNTIES: HAMILTON TO HOST SUBSTANCE ABUSE FORUM -** Heroin and forms of LSD are making a comeback across Central Indiana (Kirschner, *WTHR-TV*). Sometimes, the impact is deadly. We talk about the Blue Pledge and empowering you to keep yourself and your family safe. This has to be one of the most important conversations you can have as a family, and that is to know what is out there when it comes to your kids and drugs. What communities across Indiana are seeing — what police agencies are seeing making a comeback — is the popularity of heroin and a synthetic form of LSD known as n-bomb. It is the synthetic form of the drug that claimed the life of a Johnson County teen earlier this year. Sam Motsay was found dead at a friend's house. Police say there is a reason kids are tempted to buy these kinds of drugs. "What we're hearing from kids who are taking these substances is that they don't think they'll test positive in a drug screen," said Hamilton County Sheriff Mark Bowen. "But they're even more deadly than real thing. You don't know the potency, you don't know what you're ingesting. It's like playing Russian roulette. You just don't know."

**COUNTIES: DRUG ABUSE ON THE RISE IN HAMILTON -** Hamilton County Sheriff Mark Bowen is sounding the alarm after noticing a disturbing trend in the county. According to Bowen, underage drinking, drug arrests, and overdoses are on the rise (Grace, *WISH-TV*). "We are seeing an increase throughout the community heroin is what we are starting to see an increase," said Hamilton County Sheriff Mark Bowen…In 2013, eight drug overdose cases were reported, in 2014 that number jumped to 16. Deputies also gave stats on operating while intoxicated cases in 2013 and there were 159 cases, so far this year there has been 177. "There is a misconception that drugs and alcohol only affects a certain part of society, but we need Hamilton County residents to see the impact of these threats and to join in the fight against the problem," said Bowen.

**COUNTIES: WAYNE WILL TAKE AMBULANCE BIDS NEXT MONTH -** Wayne County officials will seek bids next month for ambulance service in the county, but whether that service will include the city of Richmond remains to be seen (Engle,*Richmond Palladium-Item*). The Wayne County Board of Commissioners on Wednesday approved issuing a request for proposals (RFP) in September for companies to provide ambulance service to areas formerly covered by Rural/Metro Ambulance Service. Rural/Metro officials last week announced they are pulling out of most of Indiana because of low volumes of runs, low Medicaid reimbursement and lack of pay by indigent clients. Rural/Metro is expected to end service Oct. 19 in Wayne County even though it has a contract with the county to provide service through 2015. The commissioners hope to have an RFP ready for the public by early September and then accept bids until Oct. 1. President Denny Burns said he hopes the commissioners can award a contract on Oct. 8.

**Scott.A.Milkey**

**From:** McGuffee, Tyler Ann
**Sent:** Thursday, August 07, 2014 10:02 AM
**To:** Charles Hiltunen, III;Hahn, Trenton F. (BPAG);O'Brien Michael R.;Sladek, Brian (National Office);Guadalupe, Michele;Mike Rinebold;Indiana Academy of Family Physicians Foundation - Missy Lewis;Mike Brady;Allison Taylor;Daniel.Eichenberger@fmhhs.com;jcaster@inaap.org;Taylor, Allison L.;Tony Gillespie;Steve McCaffrey;Herndon, Brianna
**Subject:** Prior Authorization Forms in various states

# Forms

By request, I have received the uniform and electronic prior authorization forms for the following states and included the standard used as well as the top carriers within those states.

| State | Standard Used | Area | Top Carriers |
|---|---|---|---|
| Vermont | NCPDP ePA | Medical only; each insurer can use own form for Rx | BCBS Vermont<br><br>MVP Health |
| Massachusetts | Legislation Uniform/Electronic | Medical only | Neighborhood Health Plan<br><br>Tufts Health Plan |
| Washington | NDCDP Study | Medical | Premera Blue Cross<br><br>Coordinated Care Health |
| Oregon | Legislation Uniform/Electronic | Medical | Moda Health<br><br>Kaiser Permanente |
| California | Legislation Uniform/Electronic | Rx only | Anthem Blue Cross<br><br>Blue Shield of California |
| Minnesota | NCPDP ePA | Rx only | Preferred One Health Insurance<br><br>BCBS Minnesota |
| New Mexico | NCPDP ePA | Rx only | BCBS New Mexico<br><br>New Mexico Health Connections |
| New York | Legislation Uniform Only | Medicaid | Empire BCBS |

| | | | |
|---|---|---|---|
| | | | Health Republic Insurance of NY |

**Scott.A.Milkey**

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**From:** Charles Hiltunen, III <chiltunen@[redacted]>
**Sent:** Sunday, July 27, 2014 8:01 AM
**To:** Robertson, Stephen W.;Korty, Tina;McGuffee, Tyler Ann;Hahn, Trenton F. (BPAG);O'Brien Michael R.;Sladek, Brian (National Office);Guadalupe, Michele;Mike Rinebold;Indiana Academy of Family Physicians Foundation - Missy Lewis;Mike Brady;Allison Taylor;Daniel.Eichenberger@fmhhs.com;jcaster@inaap.org;Taylor, Allison L.;Tony Gillespie;Steve McCaffrey
**Subject:** Re: Prior Authorization Follow Up Call

Attached please find a summary of other states' activities regarding prior authorization, outline of the MA PA reform language, and general description of the NCPDP e-PA efforts for your review.

Thank you for your participation in this collabor

**Scott.A.Milkey**

**From:** Quyle, Lindsay
**Sent:** Friday, July 25, 2014 8:33 AM
**To:** Quyle, Lindsay;Cleveland, Bridget;Ahearn, Mark;Atkins, Chris;Bailey, Brian (OMB);Bauer, Zachary C;Berry, Adam (GOV);Brooks, Kara D;Brown, Hannah;Marshall, Sara (Cardwell);Joyner Burroughs (Cissel), Jackie;Crabtree, Chris;Craig, Lindsey M;Czarniecki, Cary (Lani);Denault, Christina;Espich, Jeff;Fritz, Pam (GOV);Jarmula, Ryan L;Kane, Kristen;Kossack, Andrew;Morales, Cesar (Diego);Myers, Janille;Neale, Brian S;Pavlik, Jennifer L;Pitcock, Josh;Price, Kendra;Schilb, Veronica J;Schmidt, Daniel W;Simcox, Stephen;Streeter, Ryan T;Trexler, Christina;Fernandez, Marilyn;Hodgin, Stephanie;Rosebrough, Dennis (LG);Cardwell, Jeffery;Dowd, Jaclyn (CECI);Keefer, Sean (GOV);Norton, Erin (Ladd);Johnson, Matt (GOV);Heater, Ryan;Fiddian-Green, Claire (CECI);Rosebrough, Dennis;Mantravadi, Adarsh V;Rosebrough, Dennis (LG);Workman, James D;McKinney, Ted;Bausman, David;Atterholt, Jim;Davidson, Brenden;Myers, Janille;Mckinney, Caroline;Fox, Joseph R;ramplesstraveled@[redacted]
**Subject:** [Gov Clips] Howey
**Attachments:** 7-25-14_HPI Daily.pdf

Thank you,

Lindsay Quyle, *Staff Assistant*
**Office of Govenor Mike Pence**
lquyle@gov.in.gov
Phone: (317) 232-1198
Fax: (317) 232-3443

# July 25, 2014 HPI Daily Wire

Friday, July 25, 2014 8:01 AM

**INDIANA MEDICAID BACKLOG:** More than 80,000 Hoosiers had their applications for Medicaid health benefits stuck in a backlog in May, prompting the federal government to launch a special review this month (Wall, *Indianapolis Business Journal*). The federal Centers for Medicare & Medicaid Services, known as CMS, sent a letter to Indiana officials July 9 expressing concern about the delays. Indiana was one of 13 states to receive the letters. If not eliminated, the backlog could create problems for Gov. Mike Pence later this year, when he hopes to enroll as many as 350,000 into an expanded Healthy Indiana Plan to provide health care coverage for low-income Hoosiers. Joe Moser, director of the Indiana Medicaid program, said his staff has already whittled down the backlog by roughly half. Indiana is scheduled to meet with CMS officials next week to begin the review process. "We made a significant dent in pending applications in the last two months," Moser said, estimating the backlog of 82,500 applications in May had dropped by more than 20,000 in June and by another 20,000 or more in July. "That may alleviate any concerns they may have had." Still, Moser acknowledged, eliminating the backlog before expanding the Healthy Indiana Plan into what Pence calls HIP 2.0 is a critical goal for the state. The HIP 2.0 plan, proposed in May, is awaiting approval from CMS. "Our goal here is to clear the decks on any pending applications when HIP 2.0 starts," Moser said. The backlog of applications developed even though Indiana was one of 24 states that did not expand eligibility for Medicaid this year, as called for by President Obama's health reform law, known as Obamacare. Indiana experienced problems from several issues, including the technical difficulties suffered by Healthcare.gov, the website created by Obamacare to help Americans sign up for private health insurance or Medicaid. The state's progress on those applications can be seen in its monthly enrollment data. Enrollment dipped in January to 1.06 million Hoosiers, but by June had surged by nearly 52,000 to 1.11 million. Moser attributed the increase to Obamacare's tax on individuals who do not obtain health coverage as well as the attention the law brought to the expansion of health insurance. Meanwhile, another problem developed because Obamacare required states to adopt a new method for calculating incomes of Medicaid applicants. That new method is known as Modified Adjusted Gross Income, or MAGI. Jim Gavin, a spokesman for the Indiana Medicaid program, said the MAGI rules lengthened the application, adding about 30 percent more processing time for each.

**FEDS ORDER STOP TO HIP EXPANSION:** The federal Centers for Medicare and Medicaid Services (CMS) has authorized the Indiana Family and Social Services Administration (FSSA) to stop enrollment into the existing Healthy Indiana Plan (*Howey Politics Indiana*). Enrollment in the current Healthy Indiana Plan has reached the point where funding from Indiana's tobacco tax cannot support additional enrollees. Approximately 52,400 low-income Hoosiers are receiving health coverage through the

high deductible, consumer-driven program funded by the state's 44-cents per pack tobacco tax and federal Medicaid dollars (*NWI Times*). The program's capacity is an average of 45,000 participants per month for the entire calendar year, according to the Family and Social Services Administration.In approving the Healthy Indiana Plan waiver renewal last year, CMS agreed to allow Indiana to adjust eligibility during the year if needed to ensure enrollment would not exceed available revenue. Should enrollment drop significantly from current numbers, it is possible that FSSA would begin to accept applications again in 2014. If this occurs, information on applying would appear on FSSA's Healthy Indiana Plan website, www.HIP.IN.gov. Meanwhile, the Pence administration continues to work closely with the Centers for Medicare and Medicaid Services (CMS) on its proposal to expand the successful program to hundreds of thousands of uninsured Hoosiers starting in 2015. A formal waiver application outlining the proposal, known as "HIP 2.0," was submitted July 3, and discussions have continued since. "We remain hopeful for a timely response so that more low-income, uninsured Hoosiers will have the option of participating in the Healthy Indiana Plan," said Joe Moser, Indiana Medicaid Director. "Unlike our current program, which has reached its peak capacity, HIP 2.0 would not be solely limited by the revenue from Indiana's tobacco tax." Senate Minority Leader Tim Lanane was critical of Gov. Mike Pence with the news. "Once again we see how the governor's reluctance to expand Medicaid has become a disservice to Hoosier families," said Lanane. "For years, the Senate Democrats have been pushing for a plan to expand health care to over 400,000 working Hoosiers. If we had just put a plan into place sooner, we could have avoided these restrictions which now block the already limited number of HIP enrollees from the important health care access they need. I appreciate the governor's recent commitment to working with the federal government on his new proposal, but once again, his indecision on how to expand health care coverage under the Affordable Care Act has left too many Hoosiers behind."

**COAST GUARD FINDS PLAINFIELD TEEN'S PLANE WRECKAGE:** The U.S. Coast Guard says crews have found wreckage from an airplane piloted by an Indiana teenager who was killed when he crashed during an around-the-world flight (*Associated Press*). Coast Guard spokesman Gene Maestas in Honolulu says portions of the single-engine plane's fuselage were recovered Wednesday night in the Pacific Ocean off the coast of American Samoa (WSBT-TV). The body of 17-year-old pilot Haris Suleman was found shortly after Tuesday's crash. Maestes says crews are still searching for the body of 58-year-old Babar Suleman, who was traveling with his son. Haris Suleman had hoped to set the record for the fastest circumnavigation around the world in a single-engine airplane with the youngest pilot in command. The Sulemans left Indiana on June 19 and were expected to arrive back in the states Saturday.

**BENNETT DISCUSSES A TO F ALLEGATIONS:** After the state ethics committee found Tony Bennett not guilty of adjusting A-F letter grades two years ago in an unethical way, Bennett admits Indiana's accountability system is confusing and contributed to the skepticism around those allegations (McInergy, *StateImpact*). The accusation against Bennett regarding the A-F system was that he changed the letter grade for Christel House Academy, a school he championed for, from a C to an A. But as Andrew Ujifusa for Education Week reports Bennett admits the complicated way schools were scored added to notion he and his staff cheated. Mr. Bennett is now an executive consultant for the Aspire longitudinal-testing system created by ACT Inc., the Iowa City, Iowa-based testing company. He said that while he is grateful for official exonerations, he's not "spiking the ball in the end zone." "Across the country, people are seeing that this is hard work," Mr. Bennett said of school accountability systems. "Our intent was to get it right. I never, ever said that our system was perfect." Indiana Inspector General David Thomas and the ethics committee did find Bennett guilty for using state resources during his 2012 re-election campaign that he lost to Glenda Ritz.

**OBAMA SAYS FLIGHT 17 'STIFFENS' EURO SPINES:** President Obama on Thursday said the downing of a Malaysia Airlines flight last week "may stiffen the spine of our Europeans partners moving forward" as the U.S. pushes for tougher sanctions on Russia (*The Hill*). In an interview on CNBC, Obama said the United States is seeing Europe "move with us" behind additional penalties on Moscow. Obama, though, acknowledged that many European counties are "concerned about a robust response to the violations of sovereignty and territorial integrity that Russia's been conducting." European nations are heavily dependent on Russia, especially for energy, but the president said despite those concerns, support is coalescing for tougher sanctions. "Not as fast as we'd like," Obama said, adding that he believed they would "get there."

**NO INVESTIGATION AT FLIGHT 17 SITE:** The rescue workers have left, and their tents are gone. The peppermint-striped plastic cordon flutters uselessly in the breeze. Farmers are harvesting wheat in a field where bodies had lain (*New York Times*). Malaysia Airlines Flight 17 was blown out of the sky one week ago on Thursday, deepening tensions between Russia and the West and thrusting at least 10 countries whose citizens were on board into the middle of a war between Ukraine's government and pro-Russian rebels, who Western intelligence officials suspect shot the plane down. Yet for all of the diplomatic frenzy that has followed the disaster, there is no sign of an investigation here. At the field in Ukraine where the exploded remnants landed, there are no guards and no recovery workers, no police officers and no investigators. Early Thursday evening, there were almost no people — just two curious 12-year-old girls looking at part of the tail of the Boeing 777. The lack of an on-the-ground investigation — and for that matter a demarcated crime scene — is perhaps not that surprising given

that the plane went down in what is essentially a no man's land where pro-Russian rebels have declared their own state. The rebels who have power in these lands have gone back to their war, uninterested in a disaster that has riveted the world.

**HPI DAILY ANALYSIS:** The Suleman tragedy is a sad, sad ending for an ambitious father and son. Circumnavigating the globe is a treacherous adventure, claiming the lives of pioneers like Amelia Earhart. Gov. Edgar Whitcomb tried sailing the globe and came up short when his boat hit a Red Sea reef. That this one took the life of 17-year-old Haris Suleman and his father, Babar deepens this tragedy. - *Brian A. Howey*

*Campaigns*

**2014: BOLAND MAKES PITCH IN TERRE HAUTE -** Indiana state treasurer hopeful Mike Boland says that if elected, he intends to be a "small-city, small-town state treasurer." In an interview during his visit to the *Tribune-Star* on Wednesday, the candidate, a Democrat, said he hoped to take "our case to the people directly," which includes ideas to help struggling Hoosiers and to promote economic development in Indiana. Boland, a former Illinois state representative and teacher now living in Fishers, is running for Indiana state treasurer against Republican Kelly Mitchell, an employee in the treasurer's office and the director of the TrustINdiana program. The current treasurer, Richard Mourdock, a Republican, is finishing his second term and cannot seek re-election. "I'm here in Terre Haute because we're promoting a platform of mine that I call Indiana First," he said. Instead of focusing on big-city banks, he said he wants to put the focus back on local, small-town banks in Indiana. He said he intends to invest more tax dollars in Indiana. "Our goal will be to put however much we can into Indiana banks first, especially in the smaller communities … to help in economic development," Boland said, because local residents know best what their communities need, he added. "I want to be the small-city, small-town state treasurer," he said. Through a second part of his platform — "Link Deposit" — Boland said he aims to help college students, minorities and small business owners. For example, he said, his administration will try to reach an agreement with banks to provide lower interest rates to college students in exchange for depositing state funds into these local banks. "So they don't just graduate with a giant debt," he said. "We want to help those students."

**2016: QUAYLE TO HEADLINE COATS FUNDRAISER -** Former vice president Dan Quayle will headline a fundraiser for U.S. Sen. Dan Coats from 5:30 to 7:30 p.m. Sept. 18 at Meridian Hills Country Club (*Howey Politics Indiana*). Sponsorship levels range

from $2,600 to $100, and students can gain access for $25 with student ID. RSVP to Melissa Thompson at melissa@afhathaway.com or call 317.536.6900.

*Congress*

**HOUSE REPUBLICANS ANXIOUS OVER NO BORDER BILL:** House Republicans are growing anxious about leaving town for the August recess without passing a border bill (*The Hill*). Ahead of a pivotal conference meeting Friday morning, rank-and-file lawmakers are openly fretting about the questions they would face from constituents if they break from legislative work without taking action to address the surge of child migrants into the United States. Many argue that if they fail to pass a bill, even one that is a total non-starter with Democrats, they'll give President Obama five weeks of open airtime to pound them as do-nothing obstructionists. "It needs to be passed before we go to the August constituent work period. I don't think we ought to go home until we've dealt with it," said Rep. Blake Farenthold (R-Texas). "The president has done a proposal, and if we don't act on that, or reject that and don't come up with a solution of our own, public opinion will swing against us. And we've already got such great approval ratings. "I was talking to one member who said, 'Yea, if we don't do anything, I'm canceling all my town halls,' " he added. While a working group presented recommendations for changes to border policy at a Wednesday meeting, House Republicans have yet to produce legislation that could be paired with a $1.5 billion spending bill crafted by appropriators. House Appropriations Committee Chairman Hal Rogers (R-Ky.) said Thursday he did not expect a border bill would be released until the beginning of next week, at the earliest. The Republicans pressing for action on a border bill are at odds with the conservative wing of the House. Those members argue that the right move is to do nothing at all, and force the president to address a problem he created with his lax immigration policies. Sen. Ted Cruz (R-Texas) met with a group of over 20 House conservatives Wednesday, where he pushed them to not pass a spending package for the border. He warned that Senate Democrats would take their bill, replace it with their own priorities, and send it back.

**WALORSKI APPEALS FOR BIPARTISAN VA COOPERATION -** U.S. Rep. Jackie Walorski (IN-02), a member of the Veterans Affairs Conference Committee and House Veterans' Affairs Committee, released the following statement after meeting with conferees this afternoon: "Today I want to reiterate the sense of urgency this conference committee needs to have. Millions of America's veterans depend on the Department of Veterans Affairs (VA) for care and support, and this bicameral and bipartisan committee must work together to find a solution. "I've said the same thing

over and over again - this issue isn't partisan and it's not political – it's American. In order to solve these problems, we must work together and change the culture of the VA and say that today is a different day. We are standing together and helping our vets. "I urge my colleagues, regardless of party or politics to work together and pass a bill. We are all here because we care, and we owe it to our veterans to provide them with nothing but the best." *(Howey Politics Indiana*)

**DONNELLY SAYS CONGRESS SAVED MLB HALL OF FAME:** A two-time MVP outfielder and a United States senator say the congressional hearings on steroids in baseball nearly a decade ago had a direct impact on preventing players tainted by the baseball's steroids era from being considered for the Hall of Fame (*ABC News)*. Sen. Joe Donnelly, D-Ind., told the ESPN's Perspectives podcast "Capital Games" that while he thought at the time the hearings shouldn't have been a congressional priority, they doomed the candidacies of high-profile players like Barry Bonds, Roger Clemens, Mark McGwire, Rafael Palmeiro, and Sammy Sosa. That, in part, paved the way for this weekend's crop of three clean players from the same era gaining induction in the Hall. "What I think the hearing helped do was, that the American people looked up and said, 'You know, it's maybe the first time that it really hit us between the eyes that we have a real problem here.' And I think it helped to change things," said Donnelly.

**LUBBERS TESTIFIES ON HIGHER ED:** Indiana's commissioner for higher education today went before a U.S. Senate committee where she stressed the importance of funding higher education and explained the state's plan to boost college degree attainment (*Indiana Public Media*). The testimony was part of a two-hour hearing, where senators heard from education leaders on state funding for education, loan repayment, college affordability and simplifying the aid application system. In her testimony, Teresa Lubbers stressed the value of Indiana's performance-based appropriations for state colleges. "It's important to pay for what you value," she said. "In Indiana, we value more degrees, more students graduating on time, more at-risk students graduating, more high-impact degrees. Lubbers says costs are escalating unnecessarily as students take more than four years to complete their degree. She says the Indiana commission is now working with state colleges and universities on a campaign to urge students to take at least 15 credits per semester. "Indiana State University now alerts students who are falling short of meeting the state's new credit completion requirements—offering them free summer tuition and discounted housing so they can catch up," Lubbers said.

**RYAN TOUTS NEW POVERTY PROGRAM:** Representative Paul D. Ryan, Republican of Wisconsin, outlined a plan to combat poverty on Thursday that would consolidate a dozen programs into a single "Opportunity Grant" that largely shifts antipoverty efforts from the federal government to the states (*New York Times)*. Mr. Ryan, the chairman of the House Budget Committee and a leading voice in his party on fiscal matters, said in a speech at the American Enterprise Institute that the federal government represents the "rear guard — it protects the supply lines." "The people on the ground, they're the vanguard," he continued. "They fight poverty on the front lines." Mr. Ryan's proposal gives new policy backbone to Republicans' recent promises to address poverty and is part of a broader political strategy to increase the party's appeal. This has given Mr. Ryan, the Republican nominee for vice president in 2012, the opportunity to show that he and his party are as concerned about the poor as Democrats are while offering a drastically different approach to addressing poverty. His plan includes a mix of both traditional Republican tax proposals to expand the earned-income tax credit and reduce regulations and some new commitments to reducing criminal sentencing and recidivism. Other Republicans, like Senator Rand Paul of Kentucky and Senator Marco Rubio of Florida, who, like Mr. Ryan are considering a 2016 presidential run, have echoed his call to broaden their party's appeal. Mr. Rubio spoke about broken families at Catholic University of America in Washington on Wednesday, and Mr. Paul will address the National Urban League in Cincinnati on Friday.

**McCAIN CALLS ARIZONA EXECUTION 'TORTURE':** A botched execution in Arizona on Wednesday amounted to "torture," said the state's senior senator John McCain (*Politico*). The longtime Republican lawmaker, who experienced years of torture while being held in captivity by the North Vietnamese during the Vietnam War, called the drawn-out lethal injection execution of Joseph Wood on Wednesday "terrible."

*State*

**GOVERNOR: FORBES MAGAZINE, PENCE ANNOUNCE SUMMIT -** *Forbes Magazine*, in partnership with the Gov. Mike Pence and the Indiana Economic Development Corporation, announced today that it will host "Forbes Reinventing America: The Innovation Summit," November 13, 2014, in Indianapolis. This Summit will convene hundreds of the nation's top innovators, from agriculture to aerospace to medicine to finance, to discuss how they're changing the way they do business – and the world around them. "Though America's industrial heartland has always been a place of unparalleled innovation, the recent resurgence taking place there is nothing short of extraordinary," said Steve Forbes, Chairman and Editor- in-Chief of Forbes Media. "The

Innovation Summit will be a one-of-a-kind opportunity for those leading this revolution to meet, network and learn from one other." "It's a very exciting time right now for business in our state and across the center of the country," said the Honorable Mike Pence, Governor of Indiana. "There's something truly special taking place, and it's a great time to come together and build on this success. We're thrilled to be hosting this summit with Forbes in Indiana." "We're thrilled that Forbes is recognizing the deep well of talent and strong entrepreneurial spirit in this part of the country," said Keynote Speaker Angie Hicks, Founder and Chief Marketing Officer of Angie's List. "We saw the value here in the people, the location and the business climate years ago. It's a point of pride that we have thrived here." "Indiana is at the forefront of the exciting changes taking place in America's heartland," said Victor Smith, Indiana Secretary of Commerce. "It's a great place to do business, and it's the perfect place to host a gathering like this."

**GOVERNOR: ANNUAL PENCE ABATE BIKE TOUR TODAY** - Gov. Mike Pence will join approximately 500 American Bikers Aimed Toward Education (ABATE) members and Hoosier motorcyclists tomorrow for the Annual Governor's Motorcycle Ride. The ride, which is free to all participants, helps to bring awareness to motorcycle safety in the Hoosier State and raises funds for the Indiana National Guard Relief Fund, which gives 100 percent of all donations to assist members of the Indiana National Guard and their families. "For their service, our Hoosier heroes of the Indiana National Guard deserve our utmost respect, profound gratitude and unwavering support," said Governor Pence. "I'm thrilled to join fellow Hoosier motorcyclists for my second Governor's Ride to support these courageous and dedicated men and women and their families." Pence and ABATE riders will leave the Statehouse at 9:30 a.m. and appear with Columbus Mayor Kristen Brown at 11:30, with Seymour Mayor Craig Luedeman at 1:30 and Madison Mayor Damon Welch at 4:10 p.m. in his city.

**GOVERNOR: ELLSPERMANN ANNOUNCES BLIGHT RECIPIENTS -** Lt. Governor Sue Ellspermann today announced that nine Indiana applicants have received a combined award of nearly $10.8 million to help eliminate blighted and abandoned homes in those communities through the Hardest Hit Fund Blight Elimination Program (*Howey Politics Indiana*). Cities receiving awards include: Alexandria $355,000; Anderson $1.4M; Elwood $625,000; Coatesville $15,000; Evansville $1.7M; Muncie $2.9M; and Terre Haute $650,000. Counties receiving awards include: Elkhart County $2.7M; Vigo County $425,000. These local governments and their non-profit partners are the successful applicants in the third of six rounds of funding that will make a total of $75 million available for blight elimination to reduce foreclosures and stabilize property values. The Blight Elimination Program provides an opportunity for local units of government in all 92 Indiana counties to compete for funding to prevent avoidable

foreclosures through the elimination of blighted, vacant and abandoned homes. "I am delighted the Blight Elimination Program will spur revitalization efforts across the broad range of cities and areas throughout the six counties receiving awards in Division 3," said Lt. Governor Ellspermann.

**STATEHOUSE: ZOELLER SEEKS RTW STAY -** The State of Indiana will ask for an immediate stay of a Lake County judge's ruling striking down the 2012 right-to-work statute (*Howey Politics Indiana*). Lake County Circuit Court Special Judge George Paras on July 17 ruled in the lawsuit United Steel et al. v. Zoeller et al. and found unconstitutional the right-to-work law, which prohibits charging union dues to workers who are not members of the union at that employer. Judge Paras did not stay his ruling and ordered that it take effect immediately upon its entry into the chronological case summary. Indiana Attorney General Greg Zoeller's office seeks an immediate stay of the ruling so the statute can remain in effect and the status quo can remain in place while the ruling is appealed. "Strong opinions exist on both sides about involuntary union dues, but the Attorney General's Office has a duty to defend the laws the Legislature passes from legal challenges plaintiffs file. If a trial court finds a law unconstitutional, then the appropriate action is to stay its ruling pending the appeal," Zoeller said. The Attorney General's Office already is defending the right-to-work law from a separate legal challenge, Sweeney v. Zoeller.

**MARRIAGE: BRIEFS PILING UP IN 7TH CIRCUIT -** Opponents of same-sex marriage cited political theory, social stability and even biblical text in legal briefs filed this week in federal court, where Indiana and Wisconsin are appealing rulings that overthrew their bans on gay weddings (Associated Press). At least 20 briefs have been filed in the case that's before the 7th U.S. Circuit Court of Appeals, including several filed Wednesday. Virtually all of the briefs stand up for the states. Federal judges in Indiana and Wisconsin overturned each state's gay marriage probation in separate rulings. When both states appealed, the 7th Circuit court combined the cases. Hundreds of same-sex couples were married in Indiana and Wisconsin between the time the bans were ruled unconstitutional and when federal courts issued orders staying them from taking effect. The status of those marriages remains in limbo until a final decision is reached, which many observers believe will be up to the U.S. Supreme Court.

**EDUCATION: LUBBERS TO LAUNCH NEW PROGRAM** - Indiana Commissioner for Higher Education Teresa Lubbers will join 400 Hoosier students and family members for the official launch of the state's new "15 to Finish" campaign at 10:30 a.m. (EST) on Monday, July 28th at the IUPUI Campus Center. The statewide effort is designed to

help more Indiana students graduate from college on time by completing at least 15 credits each semester (*Howey Politics Indiana*). Media are invited and encouraged to attend. There will be a short presentation to the students and family members in attendance before they begin their orientation session as part of the incoming fall class at IUPUI. Students and members of the media will have a chance to ask questions and interact with staff after the presentation.

**EDUCATION: MITCH KISSES A PIG -** Representatives from Purdue University puckered up for a good cause Thursday night at this year's Kiss-A-Pig Contest at the Tippecanoe County 4-H Fair (*WISH-TV*). This year's participants were Purdue Entomologist Tom Turpin, Dean of Agriculture Jay Akridge, President Mitch Daniels, Purdue Pete, and News 18 Meteorologist Cameron Hopman. Mitch Daniels raised the most money for the 4-H scholarship fund. Although it was a wet one, he said it was worth it for the 4-Hers. "Those who have not been able to see close up the sense of purpose and the accomplishment — a lot of work goes into bringing an animal to a county fair or putting a project together. A lot of our kids who aren't fortunate enough to be part of that program miss out on that," said Daniels.

**STATE FAIR: PETA WANTS ELEPHANT RIDES CANCELLED -** The world's largest animal rights organization is urging Indiana State Fair organizers to cancel the elephant rides that are slated to be a part of the upcoming celebration (*Indianapolis Star*). But fair officials said the rides, which have been a part of the event in the past, are run with the safety of the animals and the public in mind. People for the Ethical Treatment of Animals Foundation Deputy General Counsel Delcianna Winders calls the rides dangerous, saying in a news release that riders may be seriously injured and run the risk of contracting diseases from the elephants. She also said that elephants used for the rides are beaten with bullhooks while in captivity. "Stressed, abused elephants have been known to carry communicable disease and to lash out in frustration — and when those elephants have children on their backs, the consequences can be disastrous," Winders said in a statement. "PETA, whose motto includes 'animals are not ours to use for entertainment,' is calling on the Indiana State Fair to protect fairgoers and animals alike by refusing to host any elephant-ride providers." In a July 18 letter to Indiana State Fair officials, Winders says that Carson & Barnes Circus, the exhibitor scheduled to provide elephant rides, has a history of questionable care of elephants.

*Nation*

**WHITE HOUSE: OBAMA HITS CORPORATE 'DESERTERS' -** Lashing out at what he called "corporate deserters," President Obama on Thursday increased the pressure on Congress to approve legislation targeting companies that change their address to slash their U.S. tax bill (*The Hill)*. Obama, speaking at a technical college in Los Angeles, said corporations were taking advantage of a loophole not available to average workers — and in the process, forcing the middle-class to take up more of the tab for infrastructure and job-training programs. "I don't care if it's legal. It's wrong," Obama told the California crowd. "You don't get to choose the tax rate you pay. These companies shouldn't either." Obama pressed Congress to enact a measure making it impossible for a U.S. corporation to swallow up a smaller foreign company in order to avoid paying U.S. taxes. In the process, Obama echoed his Treasury secretary, Jack Lew, who last week called for a "new sense of economic patriotism."

**WHITE HOUSE: OBAMA SAYS FLIGHT BAN 'PRUDENT' -** President Obama on Thursday defended the Federal Aviation Administration's decision earlier in the week to ban flights to Tel Aviv, saying that it took "prudent action" based on facts and not politics or the country's relationship with Israel. In an interview with *CNBC,* Obama said the initial ban on Tuesday imposed by the FAA, days after a Malaysia Airlines flight was downed in Ukraine, "was based on Israel needing to show us that in fact it was safe for commercial airlines to fly in." When Israel worked through and completed a checklist of concerns and convinced the FAA that it was safe to land a plane there, Obama said, "we moved forward." "And by the way, the European governments in terms of the regulating their airlines, did the exact same thing," Obama added. "So I think what happened here was in light of some scary moments a couple of days ago, the FAA took some prudent action."

**WHITE HOUSE: KERRY PRESENTS GAZA PLAN -** Secretary of State John F. Kerry presented his proposal for a Gaza cease-fire to Israel and proxies for Hamas on Friday, seeking to curtail the violence that is now threatening to spread to the occupied West Bank and Jerusalem (Washington Post). Salvos from Israeli tanks and rockets from Hamas fighters continued through the early afternoon Friday as Kerry made a frenetic round of telephone calls to regional players. The Israeli security cabinet was prepared to debate the still-evolving proposal but was waiting for word on Hamas intentions. Israeli security forces braced for another round of demonstrations near the West Bank crossing between Ramallah and Jerusalem, which exploded in anger overnight.

**LAW: HEADY SUMMER, FATEFUL FALL FOR D'SOUZA** - Nobody wants the summer to end, but especially not Dinesh D'Souza (*New York Times*). In June, he published,

"America: Imagine a World Without Her," which spent a week as the No. 1 book on Amazon, and is currently No. 2 on the New York Times nonfiction best-seller list. In July, he released a companion film, which has grossed more than $12 million, already roughly the same as the total of such well-known documentaries as "Hoop Dreams" and "Roger & Me," counting inflation. But in September, he will stand before a judge in a Manhattan courtroom and face a possible prison term after pleading guilty earlier this year to a violation of campaign-finance laws. "The whole experience has been undoubtedly traumatic," Mr. D'Souza said of his prosecution. "But I'm determined not to let it deter me." Even with the prospect of jail time looming, Mr. D'Souza has emerged as the right-wing media star of the moment, a seemingly constant presence on talk radio and Fox News. During the run-up to the film's release, he appeared at screenings across the country, arriving, rock-star style, on a tour bus emblazoned with a giant image of his face.

*Local*

**CITIES: GUN USED TO KILL GARY COP STOLEN IN INDY -** Investigators on Thursday said they believe the gun used to kill Gary police Officer Jeffrey Westerfield had been stolen last year from a car in Indianapolis (*Indianapolis Star*). Carl Blount, 25, was charged Thursday with murder in Westerfield's death, Lake Criminal Court records show. The police officer, 47, was fatally shot on July 6 as he sat in his patrol car in the 2600 block of Jackson Street in Gary. Westerfield had been looking for Blount as a suspect in a domestic battery case, court records state. Someone called 911 later that morning and said a car had been sitting in the same spot for about an hour without moving. The car's headlights and spotlight were on, and Westerfield was slumped in the driver's seat. Investigators with the Northwest Indiana Major Crimes Task Force believed they identified the murder weapon after obtaining Blount's cellphone records from AT&T. They found a photo of a handgun with its serial number visible on the barrel. Detectives traced the serial number to a gun that had been stolen last September from a car in the parking lot of Bent Tree Apartments in Indianapolis. Blount's half-brother, Dontae, told investigators he gave the gun to Carl Blount, who, as a convicted felon, was prohibited from having a gun.

**CITIES: RENN FAMILY THANKS CITIZENS -** The family of fallen Indianapolis Metro Police Officer Perry Renn sent a letter Thursday thanking the community for its support in the days following Renn's shooting death on July 5 (*WTHR-TV*). This is the letter: "The Family of Officer Perry Renn would like to send our sincerest gratitude to all organizations, companies, groups and individuals that participated in honoring our loved

one, Officer Perry Renn. Thank you to Banker's Life and the Indianapolis Symphony Orchestra for providing the venue and beautiful music to which we were able to gather as a family and community to remember an Officer, husband, son and friend. To both Crown Hill Cemetery and the IMPD Honor Guard, we give you thanks for providing, arranging and participating in such a prestigious and heart touching ceremony. In addition, we truly thank and acknowledge the IMPD North District and all of the IMPD force for all their contributions, accommodations and support. The outpouring of honor, respect and support from the city and citizens of Indianapolis has been immensely uplifting in this time of loss and sadness. From the mementoes, letters and flowers placed at his car to the signs and flags held by supporters during the procession, we thank you. We are proud and honored to be part of a community that takes such initiative to honor a man they may have never encountered themselves, but take great pride in his contributions to their city. Our family cannot express how much this representation of love and support has meant during these days of healing."

**CITIES: NUKE DRILL TAKING PLACE IN INDY** - This week agencies from more than 28 states are practicing for a large scale emergency in Indianapolis. The exercise, Vibrant Response 2014, is the largest exercise ever conducted in North America. Local, state and federal agencies including the Environmental Protection Agency and the Department of Homeland Security are simulating their response to a nuclear bomb hitting Speedway (*WISH-TV*). Officials are acting through every scenario they would encounter should a nuclear bomb ever hit Indianapolis. "Every incident, every emergency, every weather emergency, fire, every bombing and terrorist attack is local. It would start at the local level, in this case in Marion county. In a situation like this, we would expect them to turn to the state very quickly. We would then turn to our federal assets very quickly," said John Erickson with the Indiana Department of Homeland Security. If a bomb were to hit Indianapolis, the Indiana Department of Homeland Security said citizens should seek shelter immediately. The most important thing to do in the first few minutes is to stay inside. "Get into a home, get in a business, where ever you're at. Don't travel. Get into a school, get as many walls as possible between you and the outside," said Erickson.

**CITIES: EVANSVILLE GETS $1.7M BLIGHT GRANT -** The City of Evansville has been awarded $1,680,000 from the Indiana Housing and Community Development Authority (IHCDA) as part of the statewide Hardest Hit Fund Blight Elimination Program. The amount represents Evansville's full request for funding (*Howey Politics Indiana*). A public hearing will be scheduled in the near future to communicate with city residents the full scope of the program. The city's Department of Metropolitan Development (DMD), the Evansville-Vanderburgh County Building Commission and Evansville Brownfield Corporation worked several months identifying properties in the city that

met the lengthy criteria for inclusion in the program, and delivered the completed grant proposal to IHCDA in June. "Today's award is tremendous news regarding the elimination of blight in our city, which will result in the removal of more than 80 abandoned structures," said Mayor Lloyd Winnecke. "These funds coupled with ongoing efforts by the city are major steps to remove blighted homes and improve the infrastructure and appearance *Post-Tribune* of our city."

**CITIES: GARY GETS $6M FOR STREET REPAIRS -** City officials Thursday awarded a $6.4 million contract to repair potholes and street damage at 55 different sites throughout the city (). The city will pay Reith-Riley $2.7 million this year and next and $1 million in 2016 for the project out of city funds. Also, Reith-Riley will subcontract the milling work to Day's Asphalt, a Gary company, and employ Gary residents on the job. The announcement comes after a rough winter, on top of years of wear and tear, decimated city streets earlier this year, Public Works Director Cloteal LaBroi said. "This is a priority for (Mayor Karen Freeman-Wilson) to get done, especially after such a bad winter," LaBroi said. "We had numerous complaints about potholes, and (Freeman-Wilson) took it upon herself to say 'Hey, we need to do something about this.' "

**CITIES: LAFAYETTE TO MERGE MENTAL HEALTH AGENCIES -** Officials announced Thursday that Mental Health America of Tippecanoe will absorb the Lafayette Crisis Center in a merger they say will boost mental health services in Greater Lafayette (*Lafayette Journal & Courier).* Since 1970, the crisis center has provided an array of services to those in crisis. Among current programs are rape and suicide survivor support groups and a 24-7 crisis hotline. In the coming weeks, those programs will be moved from the center's current location at 1244 N. 15 St. to the MHA's community building at 914 South St. MHA will become the lead agency, assuming the center's programs, two staff members and volunteers. "There are going to be some changes internally, but really no changes to the mission of the crisis center," said Barry Loftus, president of the center's board of directors. "We believe that our mission melds very well with their mission in meeting the mental health needs of the community."

**CITIES: WINNECKE HAS 'CONTENTIOUS' EPA MEETING -** A meeting Thursday between Evansville officials and federal regulators over the city's rejected plan to reduce the number of combined sewer overflows was "contentious," Mayor Lloyd Winnecke said afterward (*Evansville Courier & Press*).

**CITIES: EX-FRANKFORT COP STOLE $150K -** Former police Lt. Randy Emery, who retired in February from the Frankfort Police Department, pleaded guilty Tuesday to stealing nearly $150,000 in cash from a private company. He was given a three-year sentence, all of it suspended to probation with Indiana Department of Correction, and he was ordered to pay $110,000 in restitution. Emery had been hired by Good Oil Co. to transport cash deposits from the BP gas station at Interstate 65 and Indiana 28 to Regions Bank, court documents state. The off-duty officer kept picking up the money, but at some point he stopped depositing it at the bank. Emery said during the hearing Tuesday that he used the money to support a gambling addiction for which he's since sought help, the *Frankfort Times* reported.

**CITIES: SPEEDWAY TO GET ROUNDABOUT -** The Brickyard 400 at the Indianapolis Motor Speedway may be just a few days away, but the town of Speedway is already looking to next year's Indy 500 and a whole new gateway it's creating between the town and the track (*WTHR-TV*). The town of Speedway has made major strides in recent years beefing up Main Street, adding new businesses and making it look more welcoming. But, when race fans come for next year's Indy 500, they're going to notice bit changes and it all starts next week. It's all a part of the town's redevelopment plan that's been years in the making. Starting next week — a groundbreaking celebrating and preparing for the crown jewel — a roundabout at the intersection of 16th Street and Crawfordsville Road. "This intersection is a gateway,"said Scott Harris, executive director of the Speedway Redevelopment Commission. "It's across from the IMS administration building. With a lot of activity on Main Street, some of it racing-related-Dallara, IndyCar Experience, SFH Racing, this will create a very prominent gateway to the greatest racing venue in the world." Harris said the current intersection of 16th Street, Georgetown Road and Crawfordsville road has multiple roads coming in at different angles. "It's somewhat dysfunctional," he said. "The roundabout will solve those issues."

**CITIES: MAYOR HENRY WALKS BLOOMINGDALE -** Fort Wayne Mayor Tom Henry and City staff led a neighborhood walk in the Bloomingdale neighborhood Thursday evening *(Howey Politics Indiana*). The walk served as an opportunity to talk to and get feedback from citizens. It was Mayor Henry's second neighborhood walk of 2014. Several more walks are planned for this summer and fall. The walks are another example of Mayor Henry's commitment to engagement, innovation, and performance. The Mayor has also sought feedback and suggestions related to City government services in various ways including the City's website, Mayor's Night In events, and social media.

**COUNTIES: JUDGE RULES FOR RANDOLPH CAFO -** A judge has ruled state law protects four large hog farms from lawsuits filed by residents of an eastern Indiana county who complained about waste and foul smells from their operations (*Associated Press*). Special Judge Marianne Vorhees found that Indiana's right-to-farm law is constitutional and the residents didn't present evidence needed to allow the lawsuits to proceed against the Randolph County farms run by Goldsboro, N.C.-based Maxwell Foods, The Star Press of Muncie reported. The four farms all started hog production in 2007 or 2008 — and the county between Muncie and the Indiana-Ohio state line has seen its number of hogs more than triple in five years, to nearly 178,000 in 2012, according the to the U.S. Department of Agriculture. Rich Hailey, an attorney representing those who filed the lawsuits, said an appeal of the judge's ruling is likely. "These are industrialized facilities. They are not family farms," he said. "The uncontroverted truth is all the plaintiffs were living in those areas first (before the hog operations). Many had owned these properties for generations. These are people who grew up in the country. One day they looked out and had 4,000 to 8,000 hogs putting out 3 million gallons of untreated waste." The lawsuits accuse Maxwell and other defendants of allowing hog waste to accumulate and "noxious fumes and odors to discharge from and be sensed beyond the boundaries of their property." Indiana's right-to-farm law protects the rights of farmers to use "generally accepted" practices, including "the use of ever-changing technology."

**COUNTIES: BARTHOLOMEW OK's HOG CAFO -** A Bartholomew County zoning board has given approval to a farmer to build a confined feeding operation for 2,000 hogs (*Indiana Public Media*). Jeff Shoaf wants to build the operation near the town of Hope. Some nearby residents objected to the proposal over concerns that the facility would lower the water table in the area, cause odors and increase truck travel near their homes. Kyle Shepherd defended his father-in-law's proposal, saying hog farms are part of country living. "This isn't a metropolitan area," Shepherd said. "It might be residential zoned, but it's not a metropolitan area like Columbus is, Edinburgh is. It's not an incorporated town. It's the country." Bartholomew County recently formed a committee to examine its ordinances that regulates confined feeding operations after receiving complains from residents about proposed farms.

**COUNTIES: ELKHART GETS BLIGHT FUNDS -** The fight against blight just got a big boost in Elkhart County (Spaulding, *Elkhart Truth).* State officials announced on Thursday, July 24, that the county will receive $2.7 million to knock down blighted houses. Lt. Governor Sue Ellspermann announced nine Indiana applicants, including Elkhart County, received a combined award of nearly $10.8 million to help eliminate blighted and abandoned homes with money from the Hardest Hit Fund Blight Elimination Program. Thursday's announcement was the third in a series of awards for

Indiana communities "It's wonderful news," said Laura Coyne, coordinator of community redevelopment for Elkhart County. "It's like Christmas in July for some neighborhoods."

**COUNTIES: EX-HOWARD OFFICIAL PLEADS GUILTY -** One of two former county officials charged with theft and official misconduct was sentenced last week to a two-year suspended sentence after pleading guilty to misdemeanor charges (*Kokomo Tribune).*Darrell Reed, 52, pleaded guilty to two Class A misdemeanor conversion charges and was sentenced to one year on each charge. Special Judge Kurtis G. Fouts of Carroll County suspended the sentences and ordered Reed to serve two years of supervised probation, pay $3,600 in restitution to Howard County and pay court costs and probation fees. Howard Superior Court 2 Judge Brant Parry requested the appointment of a special judge due to a conflict of interest. Reed, who was the former county maintenance supervisor and his secretary, Diane L. Donnell were accused in January of using county funds to buy tools and personal items over several years. Donnell faces two counts of theft and official misconduct. She has a Sept. 15 pre-trial hearing and an Oct. 14 jury trial set in her case.