

## Questions Submitted for Roundtable Discussion 2/2/07

1. A provider has questioned whether the poster provided by the department regarding Universal Precautions can be retyped/reformatted, in that the original copy maintained by the facility is becoming illegible. In the context of prior instruction provided regarding this poster/information sheet, please note that there was a question in the September 2001 Roundtable Discussion as follows:

### Question #9

*“In a packet of information forwarded to providers in June 1994, regarding universal precautions, an approved model statement for public notice was included which has the ISDH address listed as 1330 W. Michigan Street. Providers were advised “although use of the included information sheet is encouraged, if it does not meet your facility’s needs, you may prepare an equivalent information sheet complying with requirements of this rule for ISDH approval. To submit facility-prepared information sheets for approval send them to Indiana State Department of Health, care of Universal Precautions Coordinator, 1330 W. Michigan Street, PO BOX 1964, Indianapolis, Indiana 46206-1964.”*

The question posed at that time was, *“Does the Department intend to update the notice with appropriate address? If not, would a facility need to send in for an approval to change the address on the notice currently in use?”*

Response provided was: “facilities do not need to receive an approval to correct the address. This form was updated August 1996 (see attached).”

**The current question at hand is “can a facility retype the information included on the form or must the exact form/posting distributed by ISDH continue to be utilized? Which would then provoke the question as to whether the facility must submit the facility-prepared information sheet for approval as per previous instruction?”**

### RESPONSE:

The original instruction and informational sheet was sent to facilities in 1994 by Dr. Bailey. ISDH will review this instruction and will then provide guidance as to instructions for use.

### 2. RE: Self Reported Medication Errors

The current unusual occurrence guidance mandates that the facility report *“medication errors that caused resident harm or require extensive monitoring for 24-48 hours.”* When a medication error occurs, the facility should respond to the error itself, assess for other residents who could potentially be affected (as well as other staff who could make the same mistake), address those issues, as well as proceed to analyze/revise systems as warranted and implement QA measures to monitor for ongoing compliance thereafter. Facilities are concerned that even though the above process is followed after a medication error requiring monitoring has occurred, due to self-reporting, a complaint survey is conducted and a finding of “actual harm” is assigned due to the fact that the event occurred. There is no dispute that the event occurred, as it was reported as such. In this current system, facilities are penalized for reporting the occurrence, regardless of the corrective actions taken. **Please clarify the logic in the facility reporting, knowing that the result (regardless of corrective actions taken) will result in a citation in that the medication error did, in fact, occur and required extensive monitoring as reported to ISDH.**

RESPONSE:

ISDH reports that less than 1% of incidents reported to ISDH are converted to on-site visits and findings in direct response to the facility reporting. Providers are reminded that, per ISDH policy, should the incident not warrant an immediate on-site visit following initial reporting, all reported incidents will eventually be reviewed during a subsequent on-site visit (e.g., annual, PSR, etc.).

It has been reported that surveyors continue to request from the facility (when visiting for annual or revisit) copies of all incidents reported since the time of last visit. This is not the manner in which reviews of reported incidents are to be conducted. If a surveyor is assigned to review an incident, he/she shall have a copy of said incident in his/her possession. Thus, surveyors will be reminded during upcoming training that it is not appropriate to request that facilities provide all copies of previously reported incidents while conducting on-site visits.

3. Within the interpretive guidance of F 329, there are examples of tools that may be used by facility staff, practitioners or consultants to determine baseline status as well as to monitor for effectiveness and potential adverse consequences. There is a disclaimer that states that the tools include, but are not limited to, the following...”

**A provider was concerned that they have utilized a dementia scale other than the scale listed in the guidance. It is the assumption of the industry that given the fact that the disclaimer states “may include, but are not limited to” that other tools are acceptable for use. Please confirm.**

RESPONSE:

As stated, the guidance states, “may include, but are not limited to.” Thus, it is at the discretion of the provider as to what type of assessment tool is to be utilized and to ensure the content is appropriate to attain the desired assessment information.

4. The interpretive guidance of F 329 addresses gradual dose reductions for antipsychotics as well as tapering for sedative hypnotics. The guidance addresses attempting a gradual dose reduction in two separate quarters (with at least one month between the attempts) unless clinically contraindicated for those residents with ordered antipsychotics. After the first year, the gradual dose reduction must be attempted annually, unless clinically contraindicated. Specifics as to psychopharmacological medication (other than antipsychotics and sedative hypnotics) are the same. For sedative/hypnotics that are used routinely and beyond the manufacturer’s recommendations for duration of use, the facility should attempt to taper the medication quarterly unless clinically contraindicated.

**The question was posed as to if a resident is already on a psychopharmacological medication (of any of the above categories) and is now to the point of annual reviews, and the dose is increased, does the clock “restart” for gradual dose reduction or tapering during at least two separate quarters due to the increase in dose, OR does the facility continue with annual attempts in that the medication itself remained the same?**

RESPONSE:

Keep in mind that the medication regimen review is conducted by the consultant pharmacist on a monthly basis, thus all medications are closely monitored for efficacy ongoing. Per the Interpretive Guidance, there is no directive to “restart” the clock when a dose is increased for a psychopharmacological medication previously ordered for the resident.

5. Within Table 1 (Medication Issues of Particular Relevance) under the heading of anti-diabetic medications, issues and concerns include a note that states: *“continued or long term need for a sliding scale insulin for non-emergency coverage may indicate inadequate blood sugar control.”*

Providers are concerned with this statement, in that many long term care residents continue to be provided insulin per sliding scale. **Should providers be concerned in regard to this note or should this be brought to the attention of the Indiana Medical Directors Association for closer review/scrutiny/education?**

RESPONSE:

It is anticipated that Residents with ordered sliding scale insulin require the same due to diabetic instability. This type of rationale should be documented in the medical record. This could be noted via monthly medication regimen reviews conducted by the consultant pharmacist, via documentation made by the physician, or other means. No further “rationale” is anticipated other than notation that the resident’s instability/fluctuating blood sugars warrant sliding scale insulin to be administered. It would, however, be anticipated that periodic lab testing would be in place to monitor the resident’s status. It is at the discretion of the provider to address the continued need of sliding scale insulin and securing of rationale explaining the same with the physician/Medical Director.

6. Within the investigative protocol for unnecessary medication-medication regimen review, section #3 (Medication Regimen Review) questions how the pharmacist approaches the medication regimen review process for short stay residents. Further, in F 425 (Pharmacy Services), under services of a licensed pharmacist, it again states: *“establish procedures that address medication regimen reviews for residents who are anticipated to stay less than 30 days or when the resident experiences an acute change of condition as identified by facility staff”*.

It was questioned by a provider that should a medication regimen review be conducted for a resident and that resident should then be discharged from the facility prior to recommendations being received and/or communicated to the physician caring for the resident, how is the facility anticipated to proceed? For example, should the recommendations be communicated to the resident and his/her responsible party (who can then address them with the physician)? Should the pharmacist’s recommendations be forwarded directly to the physician who will oversee the resident’s care after discharge from the facility (if known)? **Please clarify the expectation of ISDH in regard to follow thru with medication regimen review results for those residents with a stay less than 30 days, when recommendations are received just prior to the time of discharge, or after the discharge of the resident.**

RESPONSE:

It is anticipated that the facility will communicate the medication regimen review for the resident with a stay of less than 30 days to either the resident, responsible party, or physician who will be following the resident after discharge from the facility. The manner in which this information is communicated is at the discretion of the facility, as per facility policy. The facility should be able to exhibit how this information was communicated either via documentation in the medical record or proof of communication of said recommendations. Again, the manner in which the facility accomplishes and communicates this review should be addressed in the facility policy.

7. F 428 (Drug Regimen Review), within the overview it states, *“during the MRR, the pharmacist applies his/her understanding of medications and related cautions, actions and interaction as well as current medication advisories and information. The pharmacist provides consultation to the facility and attending physician(s) regarding the medication regimen and is an important member of the interdisciplinary team. Regulations prohibit the pharmacist from delegating the medication reviews to ancillary staff.”*

Providers have reported that there are pharmacists who employ a registered nurse to assist in the conducting of the monthly medication regimen reviews. Further, there are pharmacy students who have been known to assist the pharmacist in the conducting of medication regimen reviews. **Would these individuals be prohibited from participating in the medication regimen review if said reviews are co-signed by the pharmacist providing oversight? OR does this interpretive guidance prohibit anyone from participation other than the pharmacist?**

RESPONSE:

The Interpretive Guidance states that the pharmacist can not delegate the medication review to ancillary staff.

8. F 428 Drug Regimen Review under “response to irregularities identified in the MRR”, states,

*“for those issues that require physician intervention, the physician either accepts and acts upon the report and potential recommendations or rejects all or some of the report and provides a brief explanation of why the recommendation is rejected, such as in a dated progress note. It is not acceptable to document only that he/she disagrees with a report, without providing some basis for disagreeing”.*

Providers are concerned that the physicians’ response will be deemed inadequate by the survey team. **Please clarify what type of explanation/content will be anticipated as acceptable.**

**Secondly, in this regard, should there be communication with the Indiana Medical Directors Association regarding educating Medical Directors as to the anticipated acceptable explanation as to why a recommendation of the pharmacist is rejected?**

RESPONSE:

- A. It is anticipated that a brief explanation will be provided as to why the recommendation is rejected. If the physician fails to do this, the licensed nurse can inquire of the physician and document the physician’s verbal explanation for rejection of the consultant pharmacist’s recommendation(s). The nurse’s entry of explanation must then be signed by the physician to denote accuracy of the explanation as documented.  
It is at the discretion of the facility to address appropriate response to consultant pharmacist’s recommendation(s) with the attending physicians and/or facility Medical Director.
- B. Communication with Medical Director Association  
There is no requirement for this. If the attending physician does not concur with or take action on the report, the facility and the pharmacist should contact the facility’s Medical Director for guidance and possible intervention. A procedure should be in place if the attending physician is also the Medical Director.

9. Within the revised interpretative guidance, there are repeated references to consulting the pharmacist in regard to medication regimen review at the time of admission, re-admission, change of condition, etc.

**A provider questioned whether the facility must always contact the contracted consultant pharmacist, or whether the facility can inquire of other available pharmacists and document the same in regard to questions relative to medications, side-effects, etc.**

RESPONSE:

First, one would question why a facility would contact another pharmacist other than the consultant pharmacist, particularly if the conversation would address confidential information about the resident (e.g., diagnosis, medical condition, etc.). Thus, response to this question would be dependent upon the nature of the question being posed to a pharmacist. General questions about a medication and its potential adverse reactions might be an example of a question posed; however there is concern and the facility is cautioned in regard to ensuring confidential information will not be disclosed to an individual who is not directly responsible for the care of the resident.

10. A provider reported that their consultant pharmacist was insisting that MRRs are required to be completed in a residential setting in the same manner as in the comprehensive setting.

Note that the residential rules (Sec. 6) state, *“A consultant pharmacist shall be employed, or under contract, and shall: review the drug regimen of each resident receiving these services at least once every sixty (60) days. The medication review, recommendations, and notification of the physician, if necessary, shall be documented in accordance with the facility’s policy.”*

**Will the facility’s policy still guide the medication regimen review process for the residential setting, and the interpretive guidance apply only to comprehensive settings, or will aspects of the interpretive guidance be anticipated to be applied to the residential setting?**

RESPONSE:

The Residential Rules will continue to apply to licensed residential facilities. The recently released interpretive guidance does not apply to the Residential Rules/residential facilities. Should a facility “choose” to conduct the same reviews, etc., for both comprehensive and residential settings on their campus, this is at the facility’s discretion and per the facility’s own policy.

11. A provider has reported that their consultant pharmacist has insisted that ALL medications ordered for the residents MUST be addressed on the resident’s careplan. One might question if this opinion originates from determining the drug regimen to be free from unnecessary drugs *“without adequate indications for use.”* Also, interpretive guidance “II. Monitoring for Efficacy and Adverse Consequences” states, *“The information gathered during the initial and ongoing evaluations is essential to: -incorporate into a comprehensive care plan that reflects appropriate medication related goals and parameters for monitoring the resident’s condition, including the likely medication effects and potential for adverse consequences.”*

**Facilities have been accustomed to address medications of concern to the resident’s condition(s); however, have not (as a standard) addressed every medication ordered. Please clarify the expectations of ISDH.**

RESPONSE:

The Interpretive Guidance does not require that every medication be listed/addressed on the resident’s careplan. It is anticipated that if there is a concern in regard to a medication administered (e.g., need for specific monitoring, etc.), the same would be addressed appropriately, as the purpose of the careplan is to identify the needs of the resident and plan appropriate care in response to those needs. Presence/absence of a medication listed on the careplan could be dependent upon the applicable diagnosis and effect of the medication(s).

12. Prior interpretive guidance did not specifically address frequency of review/ reduction of antidepressant medications; however, current language addresses “all other psychopharmacological medications” as needing to be reviewed for tapering. **One would assume that antidepressants would fall into the category of “psychopharmacological medications other than antipsychotics and sedative/hypnotics,” thus would be reviewed for tapering. Please clarify.**

RESPONSE:

An antidepressant medication is considered a psychopharmacological medication, thus, would be reviewed for tapering. Keep in mind that a “review” must be conducted, however, if reduction is clinically contraindicated due to the resident’s maintenance or improvement in condition while taking the current dose of antidepressant medication, tapering is not mandated. Rather, documentation of review and rationale for continued use must be present.

13. The Train- the-Trainer program provided by ISDH to the three associations included “Job Aids.” Job Aid #10, under Sedatives/Hypnotics states: *“tapering must be attempted during the previous three quarters before it is considered clinically contraindicated for that year.”*

This language (stating, must be attempted during the previous three quarters...) does not appear in the interpretive guidance. **Was this a misprint from an earlier draft of F329, thus should be disregarded?**

RESPONSE:

CMS provided a corrected Job Aid #10 which deleted language that was not found in the Interpretive Guidance. The correct wording is, “for as long as a resident remains on a sedative/hypnotic that is used routinely and beyond the manufacturer’s recommendations for duration of use, the facility should attempt to taper the medication quarterly unless clinically contraindicated.”

14. **LTC NEWSLETTER CORRECTION:**

*It was noted that the Transfer/Discharge instruction and form distributed in the January 2007 LTC Newsletter was inadvertently in error. Please note the following:*

*-Although it is stated that the forms are for “Involuntary Transfer or Discharge,” please note that the forms are to continue to be utilized for transfers/discharges as per previous instruction and NOT for Involuntary Transfer or Discharge ONLY.*

*-The forms provided do not have the Appeal Rights listed in 12 point font as required. Thus, forms will be revised and shall be made available on the ISDH website. In the interim, providers will not be held responsible should the provider have already implemented the use of the forms provided inadvertently by ISDH. Simply, replace the forms when the revised copies are available on the website.*

15. Would you please confirm that if a resident prefers a certain brand of an item such as toothpaste or shampoo that is not provided by the facility, the resident may request the facility to reimburse them in an amount equal to the facility’s cost for the item that they do provide as part of the Medicaid per diem rate. For example, the facility provides Pepsodent toothpaste (facility cost of 50 cents per 4 oz tube.) The patient prefers Crest and has the family member purchase it from their personal needs allowance at a cost of \$1.50 for 4 oz. The patient could then request the facility to deposit 50 cents into their PNA account. Regardless of what price the patient pays for the items they prefer to use, the facility is only obligated to pay the amount that the item costs the facility.

RESPONSE:

If a resident wants a certain brand of a product that the facility does not have, the facility (or someone authorized by the resident) may secure that brand and the resident's personal funds account may only be billed for the difference (if any) between the two products. F162 Interpretive Guidelines supports this response.

16. Our DON is having some questions about staging of open areas. She has read the interpretive guidelines, but there are still some skin areas that are at times questionable. If we observe an area which is sheared or abraded (for example, tender skin which has been wiped with a washcloth), should the area be staged since it is just sheared off?

RESPONSE:

Staging of open areas applies to pressure ulcers. If the area is not from pressure, the facility would need to measure and describe the area, but staging would not be required. If the area worsens from pressure, then staging may apply.

17. We have 2 residents who scratch themselves raw, may be a dementia behavior. We lotion them liberally – do Aveeno baths, but no real success. Would thin cotton gloves like garden gloves be acceptable? Or would this be considered a restraint?

RESPONSE:

To determine if the gloves are a physical restraint, please assess the glove usage using the physical restraint definition. Physical restraints are defined as any manual method or physical or mechanical device, material, or equipment attached or adjacent to the resident's body that the individual cannot remove easily which restricts freedom of movement or normal access to one's body.

Additionally, the facility needs to rule out any clinical reasons for the scratching. Has the resident had a dermatology consult? Review of meds by the pharmacist? Environmental causes? Are the residents given activities to occupy their hands and divert their attention from scratching?

18. Are refrigerators allowed in resident rooms?

RESPONSE:

Resident refrigerators are allowed in long term care facilities in Indiana in accordance with facility policy. The facility policy should address at minimum: Appliance safety prior to use and on-going preventive maintenance, cleaning and monitoring of the refrigerator.

19. F161 – “Assurance of Financial Security” – Please clarify the survey procedure found within the interpretive guidance which states: *“if your team has any concerns about residents’ funds, check the amount of the surety bond to make sure it is at least equal to the total amount of residents’ funds, as of the most recent quarter.”*

Does this direct to look at daily balances for the most recent quarter?

There have been a few facilities cited when there have been sporadic days in a month where a large deposit was made and then withdrawn a few days later. The deposit placed the facility over the surety bond amount. However, the balance did not remain consistently above the amount (for example, at month end, the balance was always below the surety bond amount).

To ensure that this never occurs, would require the facility to carry a surety bond in an amount in extreme excess of the facility's normal month end balance, in that the facility could never truly anticipate the potential deposit of a large amount of money. Should a large deposit be made and left in the account, the facility would certainly be obligated to increase the surety bond amount accordingly.

Does the surveyor look at month/quarter end or at all daily balances of the last quarter? Please clarify.

RESPONSE:

Refer to F161 Interpretive Guidelines. Surveyors are required as part of Phase 2 survey protocol to check the amount of the surety bond to make sure it is at least equal to the total amount of resident funds, as of the most recent quarter.