TITLE 760 DEPARTMENT OF INSURANCE

Notice of Public Comment Period For Interim Rule

LSA Document #24-119

Governor's Approval Letter posted at: 20240410-IR-760240119GAA

PURPOSE OF NOTICE

The Indiana Department of Insurance (IDOI) is soliciting public comment on a rule to be temporarily added concerning the Indiana all payer claims data base (APCD). The IDOI seeks comment on the affected citations listed and any other provisions of Title 27 that may be affected by this rulemaking.

OVERVIEW

Basic Purpose and Background

The IDOI is charged with administering the APCD. The APCD is a large scale database that collects and aggregates significant amounts of health care data, including eligibility data, medical claims, pharmacy prescription drug claims, non-fee for service information, and health care provider data. The data collected by the APCD is intended to be used to help identify needs in health care and improve the quality and affordability of health care and health care coverage for Hoosiers. On September 23, 2023, the IDOI adopted a provisional rule establishing registration and data submission guidelines for health payers. To continue to administer the APCD, after seeking authorization to extend the provisional rule under IC 4-22-2.3-2, the IDOI seeks to adopt the proposed provisional rule. The provisional rule sets forth registration and data submission requirements for health payers and includes a provision allowing a civil penalty to be imposed for noncompliance with the provisional rule. The provisional rule impacts health payers, as defined in IC 27-1-44.5-2, including health insurers, pharmacy benefit managers, multiple employer welfare arrangements, and employee benefit plans subject to the federal Employee Retirement Income Security Act of 1974 (29 U.S.C. 1001 et seq.), including a third party administrator.

Statement Justifying Requirement or Cost

IC 27-1-44.5-11(a) requires the IDOI to adopt rules to implement IC 27-1-44.5. The rules must include a requirement that health payer data sources submit necessary information to the APCD administrator. The provisional rule imposes registration and data submission requirements on health payers. The civil penalty section of the provisional rule ensures appropriate accountability for reporting to the APCD. It is important to ensure the APCD collects as much data as possible to achieve its legislative purposes. Compliance with the APCD reporting requirements is intended to benefit the health of Hoosiers through better data collection and use of the data to improve health care, health care costs, and health insurance coverage.

REQUEST FOR PUBLIC COMMENTS

At this time, the IDOI is soliciting public comments for this rule. Comments may be submitted in one of the following ways:

- (1) By mail or common carrier to the following address: LSA Document #24-119 All Payer Claims Data Base
 - Meggan Brumbaugh
 General Counsel
 Indiana Department of Insurance
 311 West Washington Street, Suite 103
 Indianapolis, IN 46204

(317) 234-6476

(2) By electronic mail to mbrumbaugh@idoi.in.gov. To confirm timely delivery of submitted comments, please request a document receipt when sending the electronic mail. PLEASE NOTE: Electronic mail comments will not be considered part of the official written comment period unless they are sent to the address indicated in this notice.

COMMENT PERIOD DEADLINE

All comments must be postmarked or time stamped not later than May 10, 2024.

The rule, data, studies, or analyses referenced in the statement justifying any requirement or cost, and materials incorporated by reference (if applicable) are on file at the Indiana Department of Insurance, 311 West Washington Street, Suite 103, Indianapolis, Indiana and are available for public inspection. Copies of the rule and data, studies, or analyses referenced in the statement justifying any requirement or cost are available at the office of the Indiana Department of Insurance.

PROPOSED INTERIM RULE

- SECTION 1. The definitions in this document apply throughout this document.
- SECTION 2. "Administrator" has the meaning set forth in IC 27-1-44.5-0.2.
- SECTION 3. "APCD" or "data base" has the meaning set forth in IC 27-1-44.5-1.
- SECTION 4. "APCD-CDL™" means the common data layout for all payer claims databases, as developed by the University of New Hampshire and the National Association of Health Data Organizations, Version 2.1, released July 1, 2021, and hereby incorporated by reference. For purposes of this document, a reference to an individual's Social Security number in the APCD-CDL™ means the last four (4) digits of the individual's Social Security number.
 - SECTION 5. "Department" means the Indiana department of insurance.
- SECTION 6. "Designated submitter" means an entity designated by a health payer or voluntarily participating entity to:
 - (1) submit data to the APCD on behalf of the health payer or voluntarily participating entity; and
 - (2) receive communications from the administrator and department regarding the health payer's or voluntarily participating entity's APCD data submissions.
- SECTION 7. "Designated submitter representative" means an individual or the individuals authorized by a designated submitter to:
 - (1) submit data to the APCD on behalf of the health payer or voluntarily participating entity; and
 - (2) receive communications from the administrator and department regarding the health payer's or voluntarily participating entity's APCD data submissions.
- SECTION 8. "Eligibility file" means a file that includes data about each member residing in Indiana, based on requirements contained in the submission guide.
- SECTION 9. "ERISA" means the federal Employee Retirement Income Security Act of 1974 (29 U.S.C. 1001 et seq.).
- SECTION 10. "ERISA plan" means an employee benefit plan that is subject to ERISA. For purposes of this document, the term includes a third party administrator of an employee benefit plan.
 - SECTION 11. "Executive director" has the meaning set forth in IC 27-1-44.5-1.2.
 - SECTION 12. "Health payer" has the meaning set forth in IC 27-1-44.5-2.
 - SECTION 13. "Health plan" means health insurance coverage offered to a member by a health payer.
 - SECTION 14. "Historical and catch-up data" means:
 - (1) eligibility files;
 - (2) medical claims files;
 - (3) pharmacy claims files; and
 - (4) provider files;
- submitted to the APCD by a submitter for the period specified in this document.
- SECTION 15. "Medical claims file" means a file that includes data about medical claims and other encounter information, based on requirements contained in the submission guide.
- SECTION 16. "Member" means an individual covered by, or enrolled in a health plan administered by, a health payer.
- SECTION 17. "Pharmacy claims file" means a file that includes data about prescription medications and claims filed by pharmacies, based on requirements contained in the submission guide.
- SECTION 18. "Plan size submission threshold" means an aggregate total of at least three thousand (3,000) members under a health payer.

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SECTION 19. "Provider file" means a file that includes additional information about individuals and entities included in the medical claims file, pharmacy claims file, or eligibility file, and submitted based on requirements contained in the submission guide.

SECTION 20. "Submission guide" or "data submission guide" means the document entitled "Indiana All Payer Claims Database Data Submission Companion Guide", Version 1.1, updated September 2023 and hereby incorporated by reference, developed by the administrator setting forth the required schedules, data file format, record specifications, data elements, and definitions for submitting:

- (1) eligibility files;
- (2) medical claims files;
- (3) pharmacy claims files and
- (4) provider data files:

to the APCD.

- SECTION 21. "Submitter" includes the following:
- (1) Health payers meeting the plan size submission threshold.
- (2) Voluntarily participating entities.
- (3) Entities appointed as:
 - (A) designated submitters; or
 - (B) designated submitter representatives;

of entities described in subdivisions (1) and (2).

SECTION 22. "Third party administrator" has the meaning set forth in IC 27-1-25-1(a).

SECTION 23. "Voluntarily participating entity" means an entity:

- (1) not required to submit data;
- (2) that chooses to voluntarily submit data; and
- (3) approved by the department to submit data; to the APCD.

SECTION 24. (a) To request to become a voluntarily participating entity, an entity shall submit a request to the administrator to participate in the APCD through the data portal.

- (b) A request described in subsection (a) must include the following information related to the voluntarily participating entity:
 - (1) Business type.
 - (2) Number of members.
 - (3) Types of coverage offered.
 - (4) Contact information.
 - (c) The administrator shall notify the requesting entity of the department's determination.

SECTION 25. (a) A health payer not meeting the plan size submission threshold is exempt from the submission requirements set forth in SECTIONs 28, 29, and 34 of this document. The number of Indiana members is calculated by adding together the Indiana members in all the entity's health plans as of December 31 each calendar year. Additional changes in the data submission guide will allow an eighty (80) calendar day window to submit data after the approved and final publications of the data submission guide.

- (b) A health payer dropping below the plan size submission threshold as of December 31 shall submit data files to the APCD for data through December 31 of that calendar year. The health payer shall notify the APCD of its change in status and may elect to become a voluntarily participating entity.
- (c) A previously exempt health payer no longer exempt by meeting the plan size submission threshold as of December 31 shall submit data files to the APCD to report the next calendar year's data.
- (d) A newly created health payer meeting the plan size submission threshold December 31 of the year when it is created shall submit data files to the APCD to report the next calendar year's data.

SECTION 26. (a) If a health payer contracts with other entities to administer plan benefits, the health payer has sole responsibility for the timely submission of the data to the APCD. The health payer shall

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either:

- (1) obtain necessary data from the contracted entity and submit the data to the APCD; or
- (2) ensure the contracted entity submits the data directly to the APCD.
- (b) A health payer shall identify each contracted entity through the registration process. A contracted entity shall register under SECTION 27 or SECTION 34 of this document, as applicable. This entity is referred to as a designated submitter.
- SECTION 27. (a) A health payer shall register in the data portal and review and update, or confirm, the registration information before February 1 each year after the year of its initial registration.
- (b) When a health payer becomes subject to this document, it shall register at least sixty (60) calendar days before its first data files are due.
- (c) A voluntarily participating entity shall register to submit data to the data portal. Before registering, the entity must have been approved to submit data under SECTION 24 of this document.
 - (d) Submitters shall:
 - (1) register through the data portal;
 - (2) provide the required information as specified in the data submission guide; and
 - (3) update registration information;
- within fifteen (15) calendar days of any change in the required contact information.
- SECTION 28. (a) Submitters shall submit data files monthly through the data portal. A monthly file must be submitted by the first business day of the second month after the report month.
- (b) The following files, as specified in the data submission guide, in conjunction with the APCD-CDL™, must be submitted:
 - (1) Eligibility files.
 - (2) Medical claims files.
 - (3) Pharmacy claims files.
 - (4) Provider files.
- (c) Files must exclude data for members only enrolled in the types of coverages set forth in <u>IC 27-1-44.5-2(3)(A)</u> through <u>IC 27-1-44.5-2(3)(H)</u>.
- (d) Data files must comply with file format, technical specifications, and other standards specified in the data submission quide, in conjunction with the APCD-CDL™.
- (e) If a submitter has identified at least one (1) designated submitter or designated submitter representative to submit information directly to the data portal on their behalf, the data submission is not considered finished until the required files have been received.
- (f) Submitters shall use the data portal to submit test files to confirm and test their ability to create data files meeting the standards set forth in the data submission guide. Test files will be identified as specified in the data submission guide. Test files will not be considered to have been submitted to the APCD.
- SECTION 29. (a) A submitter shall use the test function to prepare for submitting historical and catch-up data files. This testing process must be successfully finished before July 1, 2023.
- (b) Submitters shall submit historical and catch-up data files as set forth in SECTION 28 of this document for the period beginning January 1, 2020, through July 31, 2023, before September 1, 2023. Additional changes in the data submission guide will be announced with an eighty (80) calendar day window for submitters to prepare, reprogram, test, and submit production data.
- (c) Submitters shall begin regular monthly reporting with monthly data files for August 2023 before October 3, 2023. Additional changes in the data submission guide will be announced with an eighty (80) calendar day window for submitters to prepare, reprogram, test, and submit production data.
 - SECTION 30. Data files submitted to the data portal not meeting the file intake specifications detailed

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in the data submission guide will not be accepted. Submitters will be notified within two (2) business days after submission whether a data file has been accepted or rejected.

- SECTION 31. If an administrator determines a previously accepted file contains initially unidentified errors, the administrator shall notify the submitter. The submitter shall address the issues identified by the administrator by either:
 - (1) explaining to the administrator and providing supporting documentation, as necessary, showing the file is correct as initially submitted; or
 - (2) correcting and resubmitting the file within thirty (30) calendar days after notification by the administrator.
- SECTION 32. (a) A submitter unable to submit data files meeting the standards set forth in the data submission guide may request a temporary variance to those requirements.
- (b) Variance requests may only be submitted through the data portal, and must clearly identify the following with the data submission guide requirements:
 - (1) The nature of the issues.
 - (2) The plan for correction of the issues.
 - (3) The anticipated date of compliance.
- (c) An administrator shall either approve or disapprove variance requests meeting the requirements of subsection (b) within five (5) calendar days after the date the request was submitted.
 - SECTION 33. (a) If a health payer fails to:
 - (1) submit required data to the APCD;
 - (2) submit required data passing the data quality validations or variances under the periods outlined in this document;
 - (3) register for the APCD; or
 - (4) correct submissions rejected because of errors;

the administrator shall give written notice of the nature of the violation and required steps to cure the violation to the health payer, and copy the executive director on the written notice.

- (b) If a health payer fails to provide the required information set forth in the written notice described in subsection (a) within thirty (30) calendar days after receiving the notice, the administrator shall give written notice of the failure to report to the health payer, and notify the executive director of the health payer's failure to report.
 - (c) The executive director may assess a penalty for uncured violations of up to:
 - (1) one hundred dollars (\$100) a day, for each issue, for the first thirty (30) days a health payer fails to provide the required data to the APCD; and
 - (2) one thousand dollars (\$1,000) for each day thereafter.

In determining whether to impose a penalty, the executive director may consider mitigating factors, including the reasons for the failure to report and the detrimental impact on the public purpose served by the APCD.

- (d) If the failure to perform any of the actions set forth in subsection (a) is a result of the action or inaction of a contracted entity identified as a designated submitter or a designated submitter representative, the penalty is assessed to the health payer.
 - (e) The penalties specified in this SECTION do not apply to voluntarily participating entities.
 - (f) Penalties will be deposited into the department of insurance fund created by IC 27-1-3-28.
 - SECTION 34. (a) This SECTION applies only to ERISA plans in effect after June 30, 2023.
 - (b) SECTION 29 of this document does not apply to ERISA plans.
 - (c) An ERISA plan must register to submit data to the data portal. An ERISA plan must:
 - (1) finish its initial registration with the APCD before September 1, 2023; and
 - (2) review and update, or confirm, the registration information before February 1 each year thereafter.

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- (d) A submitter shall use the test function to prepare for submitting historical and catch-up data files. This testing process must be successfully finished before November 1, 2023.
- (e) Submitters shall submit historical and catch-up data files as set forth in SECTION 28 of this document for the period beginning January 1, 2020, through December 31, 2023, before April 1, 2024.
 - (f) Submitters shall begin regular monthly reporting with monthly data files for January 2024.

SECTION 35. If a SECTION or part of a SECTION of this document, or its applicability to any person or circumstance, is held invalid by a court, the remainder of the document or the applicability of the provision to other persons or circumstances is not affected.

SECTION 36. This document expires September 30, 2024.

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Approved by Governor: March 20, 2024

Documents Incorporated by Reference: None Received by Publisher

Budget Agenda: Dated August 2023

Posted: 04/10/2024 by Legislative Services Agency

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