



Common Sense Initiative

Mike DeWine, Governor
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Business Impact Analysis

Agency, Board, or Commission Name: Ohio Department of Medicaid

Rule Contact Name and Contact Information:

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Regulation/Package Title (a general description of the rules' substantive content):

Electronic Data Interchange (EDI) trading partner enrollment and testing

Rule Number(s): 5160-1-20 (rescind) and 5160-1-20 (new) _____

Date of Submission for CSI Review: 3/2/2022

Public Comment Period End Date: 3/9/2022

Rule Type/Number of Rules:

New/ 1 rules

No Change/ rules (FYR?)

Amended/ rules (FYR?)

Rescinded/ 1 rules (FYR? no)

The Common Sense Initiative is established in R.C. 107.61 to eliminate excessive and duplicative rules and regulations that stand in the way of job creation. Under the Common Sense Initiative, agencies must balance the critical objectives of regulations that have an adverse impact on business with the costs of compliance by the regulated parties. Agencies should promote transparency, responsiveness, predictability, and flexibility while developing regulations that are fair and easy to follow. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.

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Reason for Submission

1. **R.C. 106.03 and 106.031 require agencies, when reviewing a rule, to determine whether the rule has an adverse impact on businesses as defined by R.C. 107.52. If the agency determines that it does, it must complete a business impact analysis and submit the rule for CSI review.**

Which adverse impact(s) to businesses has the agency determined the rule(s) create?

The rule(s):

- a. ☒ **Requires a license, permit, or any other prior authorization to engage in or operate a line of business.**
- b. ☒ **Imposes a criminal penalty, a civil penalty, or another sanction, or creates a cause of action for failure to comply with its terms.**
- c. ☒ **Requires specific expenditures or the report of information as a condition of compliance.**
- d. ☒ **Is likely to directly reduce the revenue or increase the expenses of the lines of business to which it will apply or applies.**

Regulatory Intent

2. **Please briefly describe the draft regulation in plain language.**

Please include the key provisions of the regulation as well as any proposed amendments.

Ohio Administrative Code rule 5160-1-20, entitled, “Electronic data interchange (EDI) trading partner enrollment and testing” is being proposed for rescission as more than 50% of the rule requires amending. This rule will be replaced with a new rule of the same number and title and will retain much of the same content from the rule to be rescinded. This rule was reviewed in preparation for the Next Generation of Ohio Medicaid Managed Care program and in response to procuring a new EDI vendor.

This rule describes and defines general provisions for covered entities (including health plans, health care clearinghouses and health care providers) to enroll as a trading partner with the Ohio Department of Medicaid (ODM). This rule outlines the trading partner responsibilities related to the submission of EDI files for testing and production in the Health Insurance Portability and Accountability Act (HIPAA) compliant EDI standard formats. Entities must submit the appropriate documentation both before testing and prior to submitting claims for production adjudication. Requirements for each phase of testing are defined, in addition to specific requirements to be met prior to obtaining approval to move to

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production adjudication. The rule informs all trading partners of their responsibility for breaches of information including being liable for any breach and their associated costs. Lastly, trading partners not actively submitting 837 files are required to submit a report on a quarterly basis of the national provider identifier (NPI) numbers for all the providers the trading partner represents.

The new rule provides the same provisions as the rescinded rule with the following changes:

- Added definitions of EDI transactions and reorganizes this section of the rule into alphabetical order. Definitions were added to accommodate EDI transactions that will be adopted by ODM in the future and with implementation of the Next Generation of Ohio Medicaid Managed Care Program and related initiatives.
- Added testing criteria
- Added more detail related to the passing criteria for specific transactions tested.
- Added a statement that ODM may terminate without notice the trading partner agreement of trading partners who do not submit or receive EDI transactions for 2 years or longer.
- Removes regulatory restrictions in accordance with Section 121.95 of the Revised Code.

3. Please list the Ohio statute(s) that authorize the agency, board or commission to adopt the rule(s) and the statute(s) that amplify that authority.

5164.02 of the Ohio Revised Code.

4. Does the regulation implement a federal requirement? Is the proposed regulation being adopted or amended to enable the state to obtain or maintain approval to administer and enforce a federal law or to participate in a federal program?

If yes, please briefly explain the source and substance of the federal requirement.

Yes. Pursuant to Section 1104 of the Affordable Care Act and 45 CFR 162.920, ODM is required to provide the capability for the use of EDI 270/271 and 276/277 transactions in real time and free of charge. HIPAA also specifies that EDI trading partners are responsible for any breach of information and will be held fully liable for any and all costs related to such a breach.

5. If the regulation includes provisions not specifically required by the federal government, please explain the rationale for exceeding the federal requirement.

There are no provisions in the rule that exceed the federal requirement.

6. What is the public purpose for this regulation (i.e., why does the Agency feel that there needs to be any regulation in this area at all)?

The purpose of this regulation is to protect private health information of Medicaid recipients and define the enrollment and testing requirements for covered entities who seek to become a Medicaid EDI trading partner. This rule ensures the integrity of ODM's data while securely and efficiently exchanging protected health information through EDI to conduct Medicaid

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business. This rule also protects the state Medicaid agency from being held financially liable for any breach of information by trading partners.

7. How will the Agency measure the success of this regulation in terms of outputs and/or outcomes?

The success of this regulation will be measured by the secure and efficient exchange of protected health information (PHI) in conducting Medicaid business. ODM will evaluate this by monitoring the enrollment, quarterly reports, and testing activities of current and potential EDI trading partners.

8. Are any of the proposed rules contained in this rule package being submitted pursuant to R.C. 101.352, 101.353, 106.032, 121.93, or 121.931?

If yes, please specify the rule number(s), the specific R.C. section requiring this submission, and a detailed explanation.

No.

Development of the Regulation

9. Please list the stakeholders included by the Agency in the development or initial review of the draft regulation.

If applicable, please include the date and medium by which the stakeholders were initially contacted.

ODM utilized its Clearance process to inform stakeholders of the intended change in rule 5160-1-20 and solicit feedback concerning the proposed changes.

10. What input was provided by the stakeholders, and how did that input affect the draft regulation being proposed by the Agency?

No concerns were expressed by stakeholders through the clearance process.

11. What scientific data was used to develop the rule or the measurable outcomes of the rule? How does this data support the regulation being proposed?

No scientific data was used in the development of this rule since it is not applicable.

12. What alternative regulations (or specific provisions within the regulation) did the Agency consider, and why did it determine that these alternatives were not appropriate? If none, why didn't the Agency consider regulatory alternatives?

No alternative regulations were considered because the regulatory intent of this rule ensures the integrity of ODM's data, protects the private health information of Medicaid recipients,

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and also protects ODM from being held financially liable for any break of information by its trading partners.

- 13. Did the Agency specifically consider a performance-based regulation? Please explain.**
Performance-based regulations define the required outcome, but don't dictate the process the regulated stakeholders must use to achieve compliance.

ODM did not consider a performance-based regulation because the technical requirements for the transmission of HIPAA mandated EDI files are highly specific and variation from these standards is likely to cause file transmission errors and inaccurate data reporting.

- 14. What measures did the Agency take to ensure that this regulation does not duplicate an existing Ohio regulation?**

All Medicaid regulations governing trading partners are promulgated and implemented by ODM. These regulations were reviewed by ODM staff to ensure there is no duplication within existing Ohio regulation.

- 15. Please describe the Agency's plan for implementation of the regulation, including any measures to ensure that the regulation is applied consistently and predictably for the regulated community.**

ODM has developed an EDI trading partner information guide that can be found on the Ohio Medicaid website at www.medicaid.ohio.gov. A transmittal letter will also be sent to the ODM stakeholder list to inform affected entities of changes to the rule.

Adverse Impact to Business

- 16. Provide a summary of the estimated cost of compliance with the rule. Specifically, please do the following:**

- a. Identify the scope of the impacted business community; and**

The scope of the impacted business community includes trading partners, entities seeking to become trading partners who submit, receive, route, and/or translate EDI transactions directly related to the administration or provision of medical assistance who seek to do business with ODM.

- b. Identify the nature of all adverse impact (e.g., fees, fines, employer time for compliance,); and**

The adverse impacts are the same for both the rescinded and the new rule. All providers must enroll as trading partners to submit and receive EDI transactions. Trading partners who are applying with ODM to transmit EDI files will need to successfully complete the file testing process. Trading partners who submit

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and receive 270/271 and 276/277 transaction sets will be asked to submit the National Provider Identification (NPI) numbers of the providers they represent. The first report is due at the time of initiating a trading partner agreement with ODM. Subsequent reports are due quarterly based on the calendar year, no later than January 1, April 1, July 1 and October 1. Trading partners will be responsible for any breach of information and be held fully liable for any and all costs relating to such breaches.

c. Quantify the expected adverse impact from the regulation.

The adverse impact can be quantified in terms of dollars, hours to comply, or other factors; and may be estimated for the entire regulated population or for a “representative business.” Please include the source for your information/estimated impact.

The costs for both the rescinded and new rule are the same. The cost of enrollment would include the provider staff time to complete the application, forms and sign the trading partner agreement. This time could vary, but usually takes no more than 20 minutes. The staff responsible is usually the business office, medical billing or coding manager. The American Academy of Professional Coders (AAPC) states the average hourly Ohio rate is around \$26.44 per hour for this position. This would result in a one-time cost of about \$9 dollars to the provider to complete the enrollment process.

Trading partners who submit and receive EDI 270/271 and 276/277 files must produce the initial and quarterly reports of NPIs represented by the trading partner. This should average about four hours over the course of a year. The staff responsible would be the business office or Medical Records and Health Information Technician. The average pay in Ohio for this position is \$19.44 per hour according to the U.S. Bureau of Labor Statistics (BLS). This would result in an additional cost of about \$78 per year.

The cost to trading partners to test the transmission of an EDI file during initial application would be the time for the worker to communicate with ODM to arrange the test and submit the files along with any troubleshooting as needed. This on average takes staff around a month with a total time averaging around forty hours. This time can vary greatly based upon the technical skill of the staff involved as well as the intricacies of the electronic system selected. The staff responsible is usually the provider’s Network and Computer Systems Administrator. The BLS states the average hourly rate for this position in Ohio is \$35.75 per hour. The projected additional one-time cost for the electronic system testing to become a trading partner using the average 40 hours of set up time multiplied by the average hourly rate of a Network and Computer systems Administrator would be around \$1430.

This rule is a requirement of HIPAA legislation. Trading partners are responsible for any breach of information and will be held fully liable for all costs relating to such a breach. The federal Office of Civil Rights decides the type of breach, the number of breaches and the resulting amount of the civil money penalty in accordance with 45 CFR 160.404.

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17. Why did the Agency determine that the regulatory intent justifies the adverse impact to the regulated business community?

The requirements in this rule ensure the security of the private health information of the Medicaid recipients. This rule ensures the integrity of ODM's data and protects ODM from being held financially liable for any breach of information on the part of trading partners.

Regulatory Flexibility

18. Does the regulation provide any exemptions or alternative means of compliance for small businesses? Please explain.

This regulation does not provide exemptions or alternative means of compliance for small businesses because of technical requirements of EDI. File transmission standards must be consistent for all current and potential trading partners and since these are industry standards and technical requirements, they are necessary to ensure the successful exchange of EDI transactions.

19. How will the agency apply Ohio Revised Code section 119.14 (waiver of fines and penalties for paperwork violations and first-time offenders) into implementation of the regulation?

No fines or penalties for paperwork violations for first time offenders exist with these regulations.

20. What resources are available to assist small businesses with compliance of the regulation?

The following resources are available to assist providers and small businesses:

E-mail: usomesedisupport@deloitte.com

Phone: 1-800-686-1516, option #4

Website: <https://medicaid.ohio.gov/wps/portal/gov/medicaid/resources-for-providers/billing/trading-partners/trading-partners>

TO BE RESCINDED

5160-1-20

Electronic data interchange (EDI) trading partner enrollment and testing.

(A) For purposes of this rule, the following definitions apply:

- (1) "Covered entity," has the same meaning as in 45 C.F.R. 160.103 (as in effect on October 1, 2018).
- (2) "Electronic data interchange (EDI) transactions" are transactions developed by standards development organizations recognized by the federal centers for medicare and medicaid services (CMS) and adopted by the Ohio department of medicaid (ODM). The different EDI transactions are defined as follows:
 - (a) "American national standards institute (ANSI) X12 820 premium payment" is a transaction used to make a payment or send a remittance advice.
 - (b) "ANSI X12 834 monthly member roster or enrollment/disenrollment in a health plan" is a transaction used to establish communication between the sponsor of the insurance product and the payer.
 - (c) "ANSI X12 835 health care claims payment/remittance advice" or "835 remittance advice" is a transaction used to make a payment or send an explanation of benefits remittance advice.
 - (d) "ANSI X12 837 health care claim" is a transaction used to submit health care claim billing or encounter information, or both, from providers (institutional, professional, or dental) of health care services to payers, either directly or via clearinghouses.
 - (e) "ANSI X12 270 eligibility, coverage, or benefit inquiry" is a transaction used to inquire about the eligibility, benefits or coverage under a subscriber's health care policy.
 - (f) "ANSI X12 271 eligibility, coverage, or benefit information response" is a transaction used to communicate information about, or changes to, eligibility, benefits, or coverage.
 - (g) "ANSI X12 276 health care claim status request" is a transaction used to request the status of a health care claim.

- (h) "ANSI X12 277 health care claim status notification" is a transaction used to respond to a request regarding the status of a health care claim.
- (i) "ANSI X12 278 health care services review information request and response" is a transaction used to transmit health care service information for the purpose of referral, certification/authorization, notification, or reporting the outcome of a health care services review.
- (3) "Trading partner" is a covered entity that submits, receives, routes, or translates EDI transactions directly related to the administration or provision of medical assistance provided under a public assistance program.

(B) Trading partners submitting EDI transactions.

- (1) Trading partners must meet the definition of a covered entity as defined in paragraph (A)(1) of this rule.
- (2) To enroll as a medicaid EDI trading partner with ODM under the Health Insurance Portability and Accountability Act (HIPAA) of 1996, and be issued a trading partner number, a covered entity must complete and submit to ODM the following:
 - (a) The electronic "Medicaid Trading Partner Form" available at <https://medicaid.ohio.gov>.
 - (b) The ODM 06306 "Designation of an 835 or 834-820 Trading Partner" form (rev. 4/2017). This form is required only if the trading partner will be receiving the 835 remittance advice on behalf of its clients.
 - (c) A trading partner agreement. Trading partner agreements must be signed by an authorized representative of the trading partner.
- (3) Once the medicaid trading partner number is assigned, the trading partner is eligible to submit claims, claim status inquiries, or eligibility inquiries for the testing process in accordance with paragraph (C) of this rule.

(C) Testing requirements.

- (1) To become an active trading partner with ODM, all trading partners must abide by all ODM testing requirements as outlined in paragraph (C)(2) and in the "Electronic Data Interchange Trading Partner Information Guide" (6/27/2017). The "Electronic Data Interchange Trading Partner Information Guide" is available at <https://medicaid.ohio.gov>.

- (2) The testing requirements that must be met in addition to the requirements listed in the "Electronic Data Interchange Trading Partner Information Guide" are as follows:
- (a) Trading partners are required to submit three files per the following transaction types that must pass testing: 837 (professional, institutional and dental), 270 (eligibility) and 276 (claim status inquiry).
 - (b) Trading partners are only required to test the transaction types that they will be submitting in production.
 - (c) Each file must contain a minimum of fifty claims, claim status inquiries, or eligibility inquiries.
 - (d) All EDI files must completely pass X12 integrity testing, HIPAA syntax, and HIPAA situation testing. Trading partners are required to modify their EDI files in accordance with any new federally mandated HIPAA standards.
 - (e) During testing, trading partners may submit one claim file per day, per 837 transaction (one professional, one institutional, and one dental) and one eligibility inquiry and one claim status inquiry per day.
 - (f) Test files are considered passing when ninety per cent of the claims submitted pass the test adjudication process. A ninety per cent pass rate must be reached for each transaction type tested.
- (D) Trading partners that are not actively submitting and receiving 837 health care claim transaction sets but who are actively submitting and receiving 270/271 and 276/277 transaction sets must provide, in a manner specified by ODM, a report of all providers by national provider identifier (NPI) that the trading partner represents. The first report is due at the time of initiating a trading partner agreement with ODM. Subsequent reports are due quarterly based on the calendar year, no later than January first, April first, July first and October first.
- (E) Trading partners shall be responsible for any breach of information and be held fully liable for any and all costs relating to such a breach.

Effective:

Five Year Review (FYR) Dates:

Certification

Date

Promulgated Under:	119.03
Statutory Authority:	5164.02
Rule Amplifies:	5162.03, 5164.02
Prior Effective Dates:	10/16/2003 (Emer.), 01/01/2004, 11/15/2004, 05/23/2007, 12/11/2011, 07/03/2014, 01/01/2020

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Electronic data interchange (EDI) trading partner enrollment and testing.

(A) For purposes of this rule, the following definitions apply:

- (1) "Covered entity" has the same meaning as in 45 C.F.R. 160.103 (as in effect on October 1, 2021).
- (2) "Electronic data interchange (EDI) transactions" are transactions developed by standards development organizations recognized by the federal centers for medicare and medicaid services (CMS) and adopted by the Ohio department of medicaid (ODM). The different EDI transactions are as follows:
 - (a) "American national standards institute (ANSI) X12 270 eligibility, coverage, or benefit inquiry" is a transaction used to inquire about the eligibility, benefits or coverage under a subscriber's health care policy.
 - (b) "ANSI X12 271 eligibility, coverage, or benefit information response" is a transaction used to communicate information about, or changes to, eligibility, benefits, or coverage.
 - (c) "ANSI X12 274 provider information" is a transaction used to exchange demographic and educational or professional qualifications about health care providers between providers, provider networks, or any other entity that maintains or verifies health care provider information.
 - (d) "ANSI X12 275 patient information" is a transaction used to communicate individual patient information requests and patient information (either solicited or unsolicited) between separate care entities in a variety of settings.
 - (e) "ANSI X12 276 health care claim status request" is a transaction used to request the status of a health care claim.
 - (f) "ANSI X12 277 health care claim status notification" is a transaction used to respond to a request regarding the status of a health care claim.
 - (g) "ANSI X12 278 health care services review information request and response" is a transaction used to transmit health care service information for the purpose of referral, certification, authorization, notification, or reporting the outcome of a health care services review.
 - (h) "ANSI X12 820 premium payment" is a transaction used to make a payment or send a remittance advice.
 - (i) "ANSI X12 834 monthly member roster or enrollment and disenrollment in a health plan" is a transaction used to establish communication between the sponsor of the insurance product and the payer.

(j) "ANSI X12 835 health care claims payment and remittance advice" or "835 remittance advice" is a transaction used to make a payment or send an explanation of benefits remittance advice.

(k) "ANSI X12 837 health care claim" is a transaction used to submit health care claim billing or encounter information, or both, from providers (institutional, professional, or dental) of health care services to payers, either directly or via clearinghouses.

(3) "Trading partner" is a covered entity as defined in 42 C.F.R. 160.103 (as in effect October 1, 2021) that submits, receives, routes, or translates EDI transactions directly related to the administration or provision of medical assistance provided under a public assistance program.

(B) Responsibilities of trading partners.

(1) To enroll as an EDI trading partner with ODM under the Health Insurance Portability and Accountability Act (HIPAA) of 1996 and be issued a trading partner number, a covered entity completes and submits to ODM the following:

(a) The electronic trading partner form available at <https://medicaid.ohio.gov>.

(b) The ODM form 06306 "Designation of an 835 or 834-820 Trading Partner" (rev. 4/2017). This form is submitted only if the trading partner will be receiving the 835 remittance advice on behalf of its clients.

(c) A trading partner agreement. Trading partner agreements are to be signed by an authorized representative of the trading partner.

(2) Once the medicaid trading partner number is assigned, the trading partner submits EDI transactions for the testing process in accordance with paragraph (C) of this rule.

(C) Testing criteria for trading partners.

(1) All trading partners are to abide by all ODM testing criteria as outlined in paragraph (C)(2) of this rule and in the trading partner enrollment and testing information guide available at www.medicareid.ohio.gov.

(2) The testing criteria to be met is as follows:

(a) Trading partners are to submit three files per the following transaction types and pass testing: 837 (professional, institutional, dental), 270 (eligibility), and 276 (claim status inquiry).

- (b) Trading partners are to test the transaction types they will be submitting in production.
- (c) For batch transactions, each file is to contain a minimum of fifty claims, claim status inquiries, or eligibility inquiries.
- (d) For real-time transactions of types 270 and 276, provide at least three real-time submissions for each transaction type.
- (e) All EDI files are to completely pass X12 integrity testing, HIPAA syntax, and HIPAA situation testing. Trading partners are expected to modify their EDI files in accordance with new federally mandated HIPAA standards.
- (f) During testing, trading partners may submit one claim file per day, per 837 transaction (one professional, one institutional, and one dental), one eligibility inquiry, and one claim status inquiry per day. Multiple tests per day are accepted for real-time transactions of types 270 and 276.

(D) Passing criteria for transactions tested.

- (1) Files containing the 270 eligibility transaction are considered passing when a successful 271 response is received without error codes 73 (invalid or missing subscriber) or 75 (subscriber not found).
- (2) Files containing the 275 patient information transaction are considered passing when a successful 999 response is received.
- (3) Files containing the 276 claim status transaction are considered passing when a valid 277 response is received with the requested claim information.
- (4) Files containing the 278 service request transaction are considered passing when a valid 278 response is received without error codes 04 (authorized quantity exceeded) or 79 (invalid participant identification).
- (5) Files containing the 837 health care claim transaction are considered passing when at least ninety per-cent of the claims are in paid status after test adjudication.

(E) Trading partners that are not actively submitting and receiving 837 health care claim transaction sets but who are actively submitting and receiving 270/271 and 276/277 transaction sets are to provide, in a manner specified by ODM, a report of all providers by national provider identifier (NPI) that the trading partner represents. The first report is due at the time of initiating a trading partner agreement with ODM. Subsequent reports are due quarterly based on the calendar year, no later than January first, April first, July first and October first. If the necessary reports

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are not submitted, the trading partner agreement will be denied or terminated, as applicable.

(F) If a trading partner does not submit or receive EDI transactions for a period of two years or longer, ODM may terminate the trading partner agreement without notice.

(G) Trading partners are responsible for any breach of information and will be held fully liable for any and all costs related to such a breach.