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Mike DeWine, Governor

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Business Impact Analysis

Agency Name: Ohio Department of Insurance					
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Rule Contact Information:	1-614-644-3463				
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Regulation/Package Title (a general description of the rules' substantive content): No Surprise Billing - Reimbursement for Unanticipated Out of Network Care					
Rule Number(s): 3901-8-	17				
Date of Submission for CSI R Public Comment Period End I					
Rule Type/Number of Rules: New/ 1 rules Amended/ rules	□ No Change/ rules (FYR?) (FYR?) □ Rescinded/ rules (FYR?)				

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

R.C. 106.03 and 106.031 requires 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.

Rule 3901-8-17 establishes requirements needed to implement sections 3902.50 through 3902.54 of the Revised Code as enacted in House Bill 388 of the 133rd General Assembly. The rule addresses definitions, parameters for reimbursement regarding unanticipated out of network care, limits on consumer cost sharing, negotiations for reimbursement, and parameters for arbitration. Details on the aforementioned list can be seen below.

Paragraph (E) - Definitions: Provides a list of definitions for the chapter.

Paragraph (F) - Parameters for reimbursement regarding unanticipated out of network care: Specifies health plan issuer shall use the same geographic regions as the metropolitan statistical area (MSA). This standard aligns to federal regulations on surprise billing. This section also requires providers to include sufficient information on a request for reimbursement in order to facilitate health plan issuers processing of claims. Also requires the application of "prompt pay" standards as specified under current law. This provision will ensure a full and timely reimbursement if parties are in agreement. If the parties are in dispute, the prompt pay standard will ensure a portion of the reimbursement is made to the health care provider for services rendered.

Paragraph (G) - Health plan issuer identification cards: Requires insurers to identify on the ID card whether the plan is subject to the Department's jurisdiction.

Paragraph (H) - Covered person cost sharing amount: Specifies consumer cost sharing rates for unanticipated out-of-network care cannot exceed the rate for services provided at an in-

network rate. The rule also prohibits the consumer's cost sharing amount from being adjusted due to subsequent negotiation or arbitrations between a health provider and the consumer's health insurer.

Paragraph (I) - Negotiations for reimbursement: The rule establishes timelines and conditions for negotiations before proceeding to arbitration.

Paragraph (J) - Parameters for Arbitration: The rule specifies the conditions, timelines, process, and payment for requesting arbitration. The rule also clarifies the procedure to bundle claims as specified under the law. Finally, the rule establishes the conditions for submitting evidence to support or dispute reimbursement rates.

The Ohio Department of Insurance is responsible for administering and enforcing many provisions of this law, which begins in January 2022.

3. Please list the Ohio statute(s) that authorize the Agency to adopt the rule(s) and the statute(s) that amplify that authority.

Sections 3902.50 to 3902.54 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?
	☐ Yes ⊠ No
	If yes, please briefly explain the source and substance of the federal requirement.
	Not applicable.

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

Not applicable.

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 the law and subsequent rule is to provide the protections for consumers against surprise billing. Multiple studies have cited as many as one in five emergency inpatient services have led to surprise medical bills (Garmon & Chartock, 2017). Traditionally, consumers would be responsible for paying these unanticipated out of networks costs directly to the healthcare provider. As of February 2021, 33 states have adopted legislation aimed at protecting consumers from surprise billing (Kona, 2021). Given these changes, states such as California and New York, have reported lower out of network care from affected specialties after passing their surprise billing law (Adler et al., 2019) and (Cooper et al., 2020).

Citations:

Garmon, C. & Chartock, B. (2017). One in five inpatient emergency department cases may lead to surprise bills. Health Affairs, 36(1), 177-81.

Kona, M. (2021). Table: State balance-billing protections, as February 5, 2021. The Commonwealth Fund.

Alder, L., Duffy, E., Ly, B., & Trish, E. (2019). California saw reduction in out-of-network care from affected specialties after 2017 surprise billing law. University of Southern California Brookings Schaeffer on Health Policy.

Cooper, Z., Morton, F. S. & Shekita, N. (2020). "Surprise! Out-of-Network Billing for Emergency Care in the United States," Journal of Political Economy, vol 128(9), pages 3626-3677.

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

Success will be measured through regular oversight of insurers and investigations of complaints submitted to the department. Additionally, the department will analyze information reported from the entity conducting arbitrations between health providers and health insurers over disputed reimbursement costs.

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

Organization	Name
American College of Emergency Physicians, Ohio Chapter	Amanda Sines – Government Advantage Group
American College of Emergency Physicians, Ohio Chapter	Holly Dorr
American Medical Response	Chris Stawasz
CareSource	Margaux Frazee
Cleveland Clinic	Blair Barnhart-Hinkle
McLaren Health Plans	Matthew Ehrlich

Ohio Ambulance and Medical Transportation Association	Lauren Huddleston – NEA Consulting
Ohio Association of Health Plans	Kelly O'Reilly
Ohio Association of Health Plans	Gretchen Blazer
Ohio Association of Health Underwriters	Barb Gerken
Ohio Emergency Medicine Physicians Alliance	Kelsey Woolard – Governmental Policy Group
Ohio Emergency Medicine Physicians Alliance	Brooke Cheney – Governmental Policy Group
Ohio Emergency Physician Alliance	Tony Cirillo MD, FACEP – U.S. Acute Care Solutions
Ohio Emergency Physician Alliance	Aron Goldfeld – Team Health
Ohio Hospital Association	Stephanie Gilligan
Ohio PIRG	Patricia Kelmar
Ohio Society of Anesthesiologists	Willa Ebersole
Ohio Society of Pathologists	Sean Kirby, MD
Ohio State Medical Association	Monica Hueckel
Ohio State Medical Association	Jennifer Hayhurst
Private EMS	Troy Judy and Chad Hawley – The Batchelder Company
Quest Diagnostics	Tony Brigano and Zach Holzapfel – Hicks Partners
Superior Ambulance	David Paragas – Barnes &Thornburg
U.S. Acute Care Association	Michael Osmundson, MD, FACEP

The department conducted a robust stakeholder campaign by soliciting comments prior to drafting the rule and conducted two rounds of rule revisions reflecting stakeholder feedback. The timeline can be seen below:

March 1, 2021: Department launches Surprise Billing web site - emails stakeholders requesting initial comments for rule framework. The requested comment period ended March 15, 2021.

March 18, 2021: Department hosts virtual meeting with health plans on surprise billing rules.

March 25, 2021: Department hosts virtual meeting with medical providers on surprise billing rules.

- May 10, 2021: Department emails stakeholders and publishes draft rule version 1 on the department's dedicated Surprise Billing web site. Stakeholders and public had until May 28, to send comments.
- June 14, 2021: Department hosts All Interested Party virtual meeting over Microsoft Teams.
- June 22, 2021: Department hosts virtual meeting with Health Plans to discuss provider-health plans' communications.
- June 25, 2021: Department emails stakeholders and publishes draft rule version 2 on the department's dedicated Surprise Billing web site. Stakeholders and public had until July 9, 2021 to send comments.
- July 13, 2021: Department hosted virtual meeting with health providers to discuss provider-health plans' communications.
- July 21, 2021: Department hosted virtual meeting with health providers to follow-up on discussion for provider-health plans' communications.
- 10. What input was provided by the stakeholders, and how did that input affect the draft regulation being proposed by the Agency?
 - Stakeholders provided written and verbal comments at various stages of the rule drafting process. Using the two rounds of stakeholder comments, the department made revisions to the draft rule to reflect consensus among the interested parties on certain topic areas. On July 1, 2021, the federal government through the Department of Health and Human Services, the Department of Labor, and the Department of the Treasury along with the Office of Personnel Management released an interim final rule implementing the federal Surprise Billing law. Some stakeholders asked for certain parts of the interim final rule be incorporated into Ohio's rule to aid organization with compliance working in multiple states.
- 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?
 - The rule incorporates stakeholders proposals and feedback throughout the period where comments were requests (March 2021-July 2021). The rule also incorprorates other states best practices to ensure a fully developed process that considers both health insurer and health providers' interests in executing a reimbursement amount in the event a patient receives unanticipated out of network care.
- 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?
 - The department is statutorily tasked with developing and establishing standards regarding reimbursement for unanticipated out of network care between health insurers and

healthcare providers. Prior to drafting the rule, the department solicited ideas from stakeholders to incorporate specific policy concerns into the rule that fits within the framework of the state and federal law. For those reasons, no other regulatory alternatives were considered.

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.*

The proposed rule sets the desired outcome of achieving a reimbursement amount for unanticipated out of network care between health insurers and healthcare providers that reflect market costs and conditions. The rule does not define the outcome, but rather establishes a standard process where providers and insurers to negotiate, and where possible arbitrate, claim amounts that reflect the market conditions to compensate providers. For this reason, the department did not consider performance based regulation.

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

The department has broad regulatory oversight of insurers and has existing laws and rules to ensure compliance with Ohio's regulatory structure. The department will rely on written notification to these entities to address any deficiencies and may refer complainants to state or federal entities who have oversight of healthcare providers.

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.

The department will continue to work with healthcare providers and insurers to educate and inform them on the new regulations. Additionally, the department will conduct a broad consumer education campaign informing consumers about their responsibilities under the new law.

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

- a. This rule impacts health insurers, and healthcare providers, when insured individuals receive healthcare services under two conditions,
 - 1. Receive emergency care at an out of network provider or at an out of network facility,
- 2. Receive unanticipated out of network care at an in network care facility, but services are rendered by an out-of-network provider.

Under these two conditions, the health provider is prohibited from balance billing the consumer for the out of network costs. Traditionally, consumers would be responsible for paying these unanticipated out of networks costs directly to the healthcare provider due to being out of network. The law and subsequent rule prevents the provider from balance billing any of these costs including additional cost-sharing.

b. As the law prohibits balance billing to the consumer for unanticipated out of network care, the new regulations represent a shift from the consumer to the health insurers and healthcare systems providing medical care. Compliance with this new shift will require additional time and resources to properly identify, document, and negotiate these unanticipated out of network claims. Healthcare providers and health insurers will likely have to deploy strategies that obtain compliance with the new law with approaches that fit their particular business model. The amount of time and approaches to responding to these unanticipated out of network claims will vary depending on the organizations business strategy, size and complexity to resolving billing claims. If the participating organizations choose to pursue arbitration, they can expect to pay a fee for the arbitration service and staff time to manage the process.

One area that healthcare providers will have to examine is their status as an out-of-network provider. The lucrative financial incentives for balance billing have been prohibited by the passage of House Bill 388 of the 133rd General Assembly. Healthcare providers will have to examine their business relationship with contracted out of network doctors and explore other alternatives.

The rule will require insurers to make modifications to their ID cards to denote the consumer's health plan is subject to Ohio's regulations on surprise billing. This change may require insurers to incur a one-time cost to implement but should aid both the insurer and healthcare providers with compliance with the obtaining reimbursement for unanticipated out of network care.

c. Quantifying exact costs is difficult given the nature of complexity of medical billing across healthcare providers and health insurers.

First organizations will have to deploy strategies on how to approach the new law. This could include examining current practices, identifying areas of impact, and anticipating the

organization responses. Organizations will have to make calculated decisions to pursue arbitration or accept the proposed reimbursement rate. Risks for pursing arbitration include increased staff time to prepare information for the arbitrator, increased costs for fees and arbitration outcomes. The possible reward for pursuing arbitration would be obtaining a favorable reimbursement amount. Ultimately, some organizations may consider changes to their pricing models and evaluation of out of network status situations.

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

As a consumer protection agency, the department has developed the rule to ensure consumers are not harmed by surprise medical bills. The rule establishes a process for insurers and healthcare providers to have the opportunity to work through a negotiation or arbitration to resolve the issue and come to an appropriate price point for these unanticipated out of network claims. The department conducted an active stakeholder feedback campaign to solicit ideas and refine policy in implementing House Bill 388 of the 133rd General Assembly. This approach has given industry time and input to shift the burden of surprise medical bills from the consumer to their perspective industries. For these reasons, adverse impacts are justified.

Regulatory Flexibility

- 18. Does the regulation provide any exemptions or alternative means of compliance for small businesses? Please explain.
 - The rule does not provide an exemption or alternative means to achieve compliance. The department's main objective was ensuring consumers had broad protections from surprise medical bills while soliciting input from affected organizations to minimize disruptions.
- 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?
 - The department will work with first-time violators to correct their violations to achieve compliance.
- 20. What resources are available to assist small businesses with compliance of the regulation?
 - The department will begin a robust education campaign during the fall of 2021 to educate everyone on the new law and regulations. As part of the campaign, the department will publish information for consumers, health insurers, and health providers on its web site. Lastly, the department will have staff available to answer questions and provide assistance as needed.