

The full analysis of economic impacts is available in the docket for this final rule (Ref. 1).

#### V. Analysis of Environmental Impact

We have determined under 21 CFR 25.30(k) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

#### VI. Paperwork Reduction Act of 1995

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

#### VII. Federalism

We have analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, we conclude that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

#### VIII. Consultation and Coordination With Indian Tribal Governments

We have analyzed this rule in accordance with the principles set forth in Executive Order 13175. We have determined that the rule does not contain policies that have substantial direct effects on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. Accordingly, we conclude that the rule does not contain policies that have tribal implications as defined in the Executive Order and, consequently, a tribal summary impact statement is not required.

#### IX. References

The following reference is on display in the Dockets Management Staff (see ADDRESSES) and is available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday. FDA has verified the website addresses, as of the date this document publishes

in the **Federal Register**, but websites are subject to change over time.

1. FDA, "Crabmeat; Amendment of Common or Usual Name Regulation: Final Regulatory Impact Analysis," 2017. Also available at <https://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm>.

#### List of Subjects in 21 CFR Part 102

Beverages, Food grades and standards, Food labeling, Frozen foods, Oils and fats, Onions, Potatoes, Seafood.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 102 is amended as follows:

#### PART 102—COMMON OR USUAL NAME FOR NONSTANDARDIZED FOODS

- 1. The authority citation for part 102 continues to read as follows:

Authority: 21 U.S.C. 321, 343, 371.

- 2. In § 102.50 revise the table to read as follows:

#### § 102.50 Crabmeat.

Scientific name of crab	Common or usual name of crabmeat
<i>Chionoecetes opilio</i> , <i>Chionoecetes tanneri</i> , <i>Chionoecetes bairdii</i> , and <i>Chionoecetes angulatus</i> .	Snow crabmeat.
<i>Erimacrus isenbeckii</i> .....	Korean variety crabmeat or Kegani crabmeat.
<i>Lithodes aequispinus</i> .....	Golden King crabmeat.
<i>Paralithodes brevipes</i> .....	King crabmeat or Hanasaki crabmeat.
<i>Paralithodes camtschaticus</i> and <i>Paralithodes platypus</i> .	King crabmeat.

Dated: April 27, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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#### DEPARTMENT OF THE TREASURY

##### Internal Revenue Service

#### 26 CFR Part 54

[TD 9744]

RIN 1545-BJ45, 1545-BJ50, 1545-BJ62, 1545-BJ57

#### DEPARTMENT OF LABOR

##### Employee Benefits Security Administration

#### 29 CFR Part 2590

RIN 1210-AB72

#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

#### 45 CFR Parts 144, 146, and 147

[CMS-9993-N]

RIN 0938-AS56

#### Clarification of Final Rules for Grandfathered Plans, Preexisting Condition Exclusions, Lifetime and Annual Limits, Rescissions, Dependent Coverage, Appeals, and Patient Protections Under the Affordable Care Act

**AGENCY:** Internal Revenue Service, Department of the Treasury; Employee Benefits Security Administration, Department of Labor; and Centers for Medicare & Medicaid Services, Department of Health and Human Services.

**ACTION:** Final rule; clarification.

**SUMMARY:** On November 18, 2015, the Departments of Labor, Health and Human Services, and the Treasury (the Departments) published a final rule in the **Federal Register** titled "Final Rules for Grandfathered Plans, Preexisting Condition Exclusions, Lifetime and Annual Limits, Rescissions, Dependent Coverage, Appeals, and Patient Protections Under the Affordable Care Act" (the November 2015 final rule), regarding, in part, the coverage of emergency services by non-grandfathered group health plans and health insurance issuers offering non-grandfathered group or individual health insurance coverage, including the requirement that non-grandfathered group health plans and health insurance issuers offering non-grandfathered group or individual health insurance coverage limit cost-sharing for out-of-network emergency services and, as part of that rule, pay at least a minimum amount for out-of-network emergency services. The American College of

Emergency Physicians (ACEP) filed a complaint in the United States District Court for the District of Columbia, which on August 31, 2017 granted in part and denied in part without prejudice ACEP's motion for summary judgment and remanded the case to the Departments to respond to the public comments from ACEP and others. In response, the Departments are issuing this notice of clarification to provide a more thorough explanation of the Departments' decision not to adopt recommendations made by ACEP and certain other commenters in the November 2015 final rule.

**DATES:** This clarification is applicable beginning May 3, 2018.

**FOR FURTHER INFORMATION CONTACT:** Amber Rivers, Employee Benefits Security Administration, Department of Labor, at (202) 693-8335; Dara R. Alderman, Internal Revenue Service, Department of the Treasury, at (202) 317-5500; and Katherine Carver, Centers for Medicare & Medicaid Services, Department of Health and Human Services, at (410) 786-1565.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

*A. The Rulemaking at Issue*

*i. Statutory Background*

The Patient Protection and Affordable Care Act (Pub. L. 111-148), was enacted on March 23, 2010; the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111-152) was enacted on March 30, 2010. These statutes are collectively referred to as "PPACA" in this document. The PPACA reorganized, amended, and added to the provisions of part A of title XXVII of the Public Health Service Act (PHS Act). PPACA also added section 715 to the Employee Retirement Income Security Act (ERISA) and section 9815 to the Internal Revenue Code (the Code) to incorporate the provisions of part A of title XXVII of the PHS Act into ERISA and the Code, and make them applicable to group health plans, and health insurance issuers providing health insurance coverage in connection with group health plans. Accordingly, sections 2701 through 2728 of the PHS Act are incorporated into the Code and ERISA.

Section 2719A of the PHS Act, which is entitled "Patient Protections," provides requirements relating to coverage of emergency services for non-grandfathered group health plans and health insurance issuers offering non-grandfathered group or individual

health insurance coverage<sup>1</sup> and states, in general, that if a group health plan, or a health insurance issuer offering group or individual health insurance coverage, provides or covers any benefits with respect to services in an emergency department of a hospital, the plan or issuer shall cover emergency services—(A) without the need for any prior authorization determination; (B) whether the health care provider furnishing such services is a participating provider with respect to such services; (C) in a manner so that, if such services are provided to a participant, beneficiary, or enrollee—(i) by a nonparticipating health care provider with or without prior authorization; or (ii) (I) such services will be provided without imposing any requirement under the plan for prior authorization of services or any limitation on coverage where the provider of services does not have a contractual relationship with the plan for the providing of services that is more restrictive than the requirements or limitations that apply to emergency department services received from providers who do have such a contractual relationship with the plan; and (II) if such services are provided out-of-network, the cost-sharing requirement (expressed as a copayment amount or coinsurance rate) is the same requirement that would apply if such services were provided in-network.

Therefore, among other things, the statute requires non-grandfathered group health plans and health insurance issuers offering non-grandfathered group or individual health insurance coverage that cover emergency services to do so even if the provider is not one of the plans' or issuers' "participating provider[s]." <sup>2</sup> In addition, section 2719A of the PHS Act requires non-grandfathered group health plans and health insurance issuers offering non-grandfathered group or individual health insurance coverage to apply the same cost-sharing requirement (expressed as copayments and coinsurance) for emergency services provided out-of-network as emergency services provided in-network; however, the statute does not expressly address how much the out-of-network provider of emergency services must be paid for

<sup>1</sup> Section 2719A of the PHS Act also provides, for non-grandfathered group health plans and health insurance issuers offering non-grandfathered group or individual health insurance coverage, rules regarding designation of primary care providers, access to pediatric care, and patient access to obstetrical and gynecological care. This document does not address those aspects of section 2719A of the PHS Act.

<sup>2</sup> See section 2719A(b)(1)(B) of the PHS Act.

performing such services by the non-grandfathered group health plan or health insurance issuer offering non-grandfathered group or individual health insurance coverage.

As background, the amount an out-of-network provider may charge for emergency services may exceed the group health plan's or health insurance issuer's "allowed amount" (the "[m]aximum amount on which payment is based for covered health care services").<sup>3</sup> The allowed amount may be subject to deductibles and other cost-sharing in terms of a fixed-amount per service and/or a coinsurance percentage of the allowed amount. In circumstances in which a provider's charge exceeds the allowed amount, some states allow an out-of-network provider to "balance bill" the patient for the amount of the provider's charge that exceeds the allowed amount.

Section 2719A of the PHS Act does not prohibit an out-of-network provider from balance billing a participant or beneficiary because although it includes a cost-sharing rule, "cost sharing" is a statutorily defined term that "does not include . . . balance billing amounts for non-network providers" and the cost-sharing requirement in section 2719A(b)(1)(C)(i)(II) of the PHS Act applies to cost sharing "expressed as a copayment amount or coinsurance rate."<sup>4</sup>

*ii. The Departments' Regulation and Related Comments*

On June 28, 2010, the Departments published an interim final rule (IFR) in the **Federal Register** titled "Patient Protection and Affordable Care Act; Requirements for Group Health Plans and Health Insurance Issuers Under the Patient Protection and Affordable Care Act Relating to Preexisting Condition Exclusions, Lifetime and Annual Limits, Rescissions, and Patient Protections," 75 FR 37188 (the June 2010 IFR). The June 2010 IFR preamble on section 2719A of the PHS Act stated, in part, that, because the statute does not require plans or issuers to cover balance billing amounts, and does not prohibit balance billing, even where the protections in the statute apply, patients may be subject to balance billing. It would defeat the purpose of the protections in the statute if a plan or

<sup>3</sup> See definition of "allowed amount" and "balance billing" in the Uniform Glossary of Health Care Coverage and Medical Terms, <https://www.dol.gov/sites/default/files/ebsa/laws-and-regulations/laws/affordable-care-act/for-employers-and-advisers/sbc-uniform-glossary-of-coverage-and-medical-terms-final.pdf>.

<sup>4</sup> See PPACA section 1302(c)(3)(B). See also 80 FR 72192, 72212-13 (Nov. 18, 2015).

issuer paid an unreasonably low amount to a provider, even while limiting the coinsurance or copayment associated with that amount to in-network amounts. To avoid the circumvention of the protections of section 2719A of the PHS Act, it is necessary that a reasonable amount be paid before a patient becomes responsible for a balance billing amount. Thus, these interim final regulations require that a reasonable amount be paid for services by some objective standard. In establishing the reasonable amount that must be paid, the Departments had to account for wide variation in how plans and issuers determine both in-network and out-of-network rates. For example, for a plan using a capitation arrangement to determine in-network payments to providers, there is no in-network rate per service.

Accordingly, these interim final regulations considered three amounts: The in-network rate, the out-of-network rate, and the Medicare rate. Specifically, a plan or issuer satisfies the copayment and coinsurance limitations in the statute if it provides benefits for out-of-network emergency services in an amount equal to the greatest of three possible amounts—(1) The amount negotiated with in-network providers for the emergency service furnished; (2) The amount for the emergency service calculated using the same method the plan generally uses to determine payments for out-of-network services (such as the usual, customary, and reasonable charges) but substituting the in-network cost-sharing provisions for the out-of-network cost-sharing provisions; or (3) The amount that would be paid under Medicare for the emergency service. Each of these three amounts is calculated excluding any in-network copayment or coinsurance imposed with respect to the participant, beneficiary, or enrollee.<sup>5</sup>

This is sometimes referred to as the “Greatest of Three” or the “GOT” regulation because it sets a floor on the amount non-grandfathered group health plans and health insurance issuers offering non-grandfathered group or individual health insurance coverage are required to pay for out-of-network emergency services under this provision at the greatest of the three listed amounts.

During the comment period for the June 2010 IFR, some commenters were in favor of the GOT regulation while others expressed concerns. Several commenters, including ACEP, objected

to the second prong of the GOT regulation, which relates to the method the plan generally uses to determine payments for out-of-network services, such as the usual, customary, and reasonable amount (henceforth referred to as the UCR amount). ACEP’s August 3, 2010 comment letter<sup>6</sup> stated the following:

. . . [W]e appreciate the clearly stated acknowledgement that allowing plans and insurers to pay emergency physicians whatever they see fit defeats the purpose of protecting patients from potentially large bills. In that light, we also support development of an objective standard to establish ‘fair payment.’ Insurers know that emergency physicians will see everyone who comes to the ED due to EMTALA responsibilities, and many leverage that fact to impose extremely low reimbursement rates. While a large majority of our members participate in nearly every plan or insurer network in their area, the primary reason they cite for not joining a plan’s network is that the plan has arbitrarily offered an in-network payment rate that fails to cover the costs of providing the service. This forces the physicians to balance bill the patients, which often results in an unsatisfactory experience for everyone but the insurer. . . .

As noted in the IF rule, ‘there is wide variation in how plans and issuers determine in [network] and out-of-network rates.’ The term ‘reasonable’ is in the eye of the beholder. For many years, usual and customary rates referred to charges or a proportion of charges. This has changed in recent years and physicians, particularly emergency physicians, have had problems with the ‘black box’ approach that commercial insurers have used to determine [the] usual and customary ‘rates’ for out-of-network providers. At this time, we are unaware of a national database that is widely available and provides timely data for objective comparisons of charges and/or costs that could be used to implement this part of the regulation. A new database, perhaps the FAIR Health data[base] that is currently being developed as a result of the settlement with Ingenix, may prove to be more timely and accurate, but any database used to establish usual and customary reasonable rates will require transparent validation, monitoring, and active enforcement by state and federal insurance officials.’

Other groups, such as Advocacy for Patients with Chronic Illness, Inc. and Lybba, the Emergency Department Practice Management Association, the American Medical Association, the American Hospital Association, the Texas Medical Association, the

Healthcare Association of New York State, and the California Chapter of ACEP, submitted similar comments expressing their concern about the lack of transparency and potential for manipulation of rates under the second prong of the GOT regulation. Like ACEP, several of these commenters referenced the FAIR Health database as a potential alternative solution.<sup>7</sup>

On November 18, 2015, the Departments finalized the regulation under section 2719A of the PHS Act, including the GOT regulation (80 FR 72192). The November 2015 final rule adopted the GOT regulation without substantive revision from the June 2010 IFR and incorporated a clarification that had been issued in subregulatory guidance.<sup>8</sup> In the November 2015 final rule, the Departments reiterated the need for the GOT regulation, and in response to the comments described above regarding the GOT regulation, the Departments stated that “[s]ome commenters expressed concern about the level of payment for out-of-network emergency services and urged the Departments to require plans and issuers to use a transparent database to determine out-of-network amounts. The Departments believe that this concern is addressed by our requirement that the amount be the greatest of the three amounts specified in [the GOT regulation].”<sup>9</sup>

#### B. Other Guidance

In response to concerns about transparency with respect to the second prong of the GOT regulation raised by ACEP in its comment and in subsequent communications to the Departments, on April 20, 2016, the Departments issued Frequently Asked Questions About Affordable Care Act Implementation Part 31, Mental Health Parity Implementation, and Women’s Health

<sup>7</sup> The FAIR Health Database was created by FAIR Health, an independent nonprofit that collects data for and manages the nation’s largest database of privately billed health insurance claims. See <https://www.fairhealth.org/about-us>.

<sup>8</sup> The final regulations incorporated guidance that had been provided in FAQs about Affordable Care Act Implementation (Part I), Q15, available at [www.dol.gov/ebsa/faqs/faq-aca.html](http://www.dol.gov/ebsa/faqs/faq-aca.html) and [https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca\\_implementation\\_faqs.html](https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs.html). The FAQ and final regulations provide that if state law prohibits balance billing, or in cases in which a group health plan or health insurance issuer is contractually responsible for balance billing amounts, plans and issuers are not required to satisfy the GOT regulation, but may not impose any copayment or coinsurance requirement for out-of-network emergency services that is higher than the copayment or coinsurance requirement that would apply if the services were provided in-network. See 26 CFR 54.9815–2719A(b)(3)(iii); 29 CFR 2590.715–2719A(b)(3)(iii); and 45 CFR 47.138(b)(3)(iii).

<sup>9</sup> 80 FR 72192, 72213 (Nov. 18, 2015).

<sup>5</sup> 75 FR at 37194 (footnote omitted). For the interim final regulation text, see 75 FR at 37225, 37232, and 37238.

<sup>6</sup> Available at <https://www.regulations.gov/contentStreamer?documentId=EBSA-2010-0016-0022&attachmentNumber=1&contentType=pdf>.

and Cancer Rights Act Implementation, which addressed, in part, the GOT regulation.<sup>10</sup> In Question & Answer number 4, the Departments clarified that a group health plan or health insurance issuer of group or individual health insurance coverage is required to disclose how it calculates the amounts under the GOT regulation, including the UCR amount. These disclosure requirements would also apply to a request for disclosure of payment amounts for in-network providers. Specifically, for group health plans subject to ERISA, documentation and data used to calculate each of the amounts under the GOT regulations for out-of-network emergency services, including the UCR amount, are considered to be instruments under which the plan is established or operated and would be subject to the disclosure provisions under section 104(b) of ERISA and 29 CFR 2520.104b-1, which generally require that such information be furnished to plan participants (or their authorized representatives) within 30 days of request.<sup>11</sup> In addition, the Department of Labor claims procedure regulations, as well as the internal claims and appeals and external review requirement under section 2719 of the PHS Act, which apply to both ERISA and non-ERISA non-grandfathered group health plans and health insurance issuers of non-grandfathered group or individual coverage, set forth rules regarding claims and appeals, including the right of a claimant (or the claimant's authorized representative) upon appeal of an adverse benefit determination (or a final internal adverse benefit determination) to be provided upon request and free of charge, reasonable access to, and copies of, all documents, records, and other information relevant to the claimant's claim for benefits, and a failure to provide or make payment of a claim in whole or in part is an adverse benefit determination.<sup>12</sup>

<sup>10</sup> See <https://www.dol.gov/sites/default/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-31.pdf>, or [https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQs-31\\_Final-4-20-16.pdf](https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQs-31_Final-4-20-16.pdf).

<sup>11</sup> See DOL Advisory Opinion 96-14A (July 31, 1996). See also FAQs about Affordable Care Act Implementation (Part XXIX) and Mental Health Parity Implementation, Q12, available at [www.dol.gov/ebsa/faqs/faq-aca29.html](http://www.dol.gov/ebsa/faqs/faq-aca29.html) and [www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQs-Part-XXIX.pdf](http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQs-Part-XXIX.pdf), providing that a plan's or issuer's characterization of information as proprietary or commercially valuable cannot be a basis for non-disclosure.

<sup>12</sup> 29 CFR 2560.503-1, 26 CFR 54.9815-2719, 29 CFR 2590.715-2719, and 45 CFR 147.136. For additional requirements for the full and fair review standard that applies under PHS Act section 2719, in addition to 29 CFR 2560.503-1(h)(2), see 26 CFR

### C. The Court's Remand Order

On May 12, 2016, ACEP filed a lawsuit against the Departments, asserting that the final GOT regulation should be invalidated because it does not ensure a reasonable payment for out-of-network emergency services as required by the statute, and that the Departments did not respond meaningfully to ACEP's comments about purported deficiencies in the regulation.<sup>13</sup>

Following briefing by both parties, on August 31, 2017, the United States District Court for the District of Columbia issued a memorandum opinion that granted in part and denied in part without prejudice ACEP's motion for summary judgment, and remanded the case to the Departments for further explanation of the November 2015 final rule.<sup>14</sup> The court concluded that the Departments did not adequately respond to comments and proposed alternatives submitted by ACEP and others regarding perceived problems with the GOT regulation. In particular, the court stated that the Departments' response in the November 2015 final rule "to numerous comments raising specific concerns about the method used in the GOT regulation for determining the amounts insurers would be required to pay for out-of-network emergency medical services—e.g., the rates' lack of transparency or their vulnerability to manipulation" did not "seriously respond to the actual concerns raised about the particular rates, and it ignore[d] altogether the proposed alternative of using a database to set payment." The court stated that its holding was "a narrow one," relating "only to the sufficiency of the Departments' response to comments and proposed alternatives."

The court did not vacate the November 2015 final rule but ordered that "this matter is remanded to the Departments of Health and Human Services, Labor, and the Treasury so that they can adequately address the comments and proposals at issue in this case. On remand, the Departments are free to exercise their discretion to supplement their explanation as they deem appropriate and to reach the same or different ultimate conclusions. At a minimum; however, the Departments are required to respond to [ACEP's] comments and proposals in a reasoned

54.9815-2719(b)(2)(ii)(C), 29 CFR 2590.715-2719(b)(2)(ii)(C), and 45 CFR 147.136(b)(2)(ii)(C) and (b)(3)(ii)(C).

<sup>13</sup> See [https://www.acep.org/Legislation-and-Advocacy/Regulatory/ACEPvsHHS\\_051216/](https://www.acep.org/Legislation-and-Advocacy/Regulatory/ACEPvsHHS_051216/).

<sup>14</sup> See *American College of Emergency Physicians v. Price, et al.*, 264 F. Supp. 3d 89 (D.D.C. 2017).

manner that 'enable[s] [the Court] to see what major issues of policy were ventilated . . . and why the agency reacted to them as it did.'" <sup>15</sup>

The Departments are issuing this document to provide the additional consideration required by the court's remand order. Specifically, the Departments are responding more fully to ACEP's written comment dated August 3, 2010 in reference to the June 2010 IFR.

## II. Further Consideration of the Departments' Final Rule in Response to the Court's Remand Order

In light of the statutory language in section 2719A of the PHS Act and the totality of the comments received in response to the June 2010 IFR, the Departments continue to believe that the implementing regulations provide a reasonable and transparent methodology to determine appropriate payments by non-grandfathered group health plans and health insurance issuers offering non-grandfathered group or individual health insurance coverage for out-of-network emergency services. ACEP's proposal that the GOT regulation require the development of a new database and/or utilization of a publicly-available database to set UCR amounts would require the Departments to extend the scope of their authority under section 2719A of the PHS Act beyond the establishment of a minimum payment amount to facilitate the cost-sharing requirements in section 2719A(b) of the PHS Act, to the development of specific provider reimbursement rates for group health plans and health insurance issuers, which is an area that, up to this point, has been reserved for the states, issuers, and health plans. Accordingly, the Departments decline to adopt such a requirement. Finally, even if the Departments were prepared to extend their authority in this manner, creating and maintaining a database or assessing, validating, and monitoring publicly available databases would be costly and time-consuming, and there is no indication in either case that such a database would provide a better method for determining UCR amounts than the methods group health plans and health insurance issuers currently use.

### A. GOT Regulation Is Reasonable and Transparent

The Departments believe that ACEP and other commenters did not provide adequate information to support their assertion that the methods used for determining the minimum payment for

<sup>15</sup> *Id.*

out-of-network emergency services under the GOT regulation are not sufficiently transparent or reasonable. In developing the GOT regulation, the Departments accounted for wide variation in how group health plans and health insurance issuers determine both in-network and out-of-network rates, and made a determination to base the GOT criteria on existing provisions of federal law. The Departments have not received any information regarding ACEP's concerns, as part of the comment record or otherwise, that persuaded us that these standards are insufficiently transparent or otherwise unreasonable, and we conclude that the methodology for determining payment amounts under all three prongs of the GOT regulation is sufficiently transparent and reasonable.

Under the GOT regulation, the three prongs work together to establish a floor on the payment amount for out-of-network emergency services, and each state generally retains authority to set higher amounts for health insurance issued within the state. The GOT regulation requires that a group health plan or health insurance issuer must pay the highest amount determined under the three prongs, which reflect amounts that the federal government itself or group health plans and health insurance issuers have established as reasonable.

The Departments determined the GOT methodology was sufficiently transparent by taking into account other federal laws which require disclosure in certain circumstances. Specifically, a group health plan subject to ERISA must disclose how it calculates a payment amount under the GOT regulation, including payment amounts to in-network providers, and the method the group health plan or health insurance issuer used to determine the UCR amount to a claimant or the claimant's authorized representative.<sup>16</sup>

Additionally, as described above, under the internal claims and appeals and external review requirements of section 2719 of the PHS Act, which apply to plans that are subject to the protections of section 2719A of the PHS Act, a claimant (or the claimant's authorized representative) upon appeal of an adverse benefit determination must be provided reasonable access to,

and copies of, all documents, records, and other information relevant to the claim for benefits, including information about the plan's determination of the UCR amount. A failure to provide or make payment of a claim in whole or in part is considered an adverse benefit determination.<sup>17</sup>

Further, the Medicare rate is transparent because the Medicare statute's provisions on setting physician payment rates are objective and detailed, and provide payment at a level that reflects the relative value of a service.<sup>18</sup> Medicare rates for physicians' services are established and reviewed every year through a rulemaking in which all physicians and other stakeholders are invited to submit public comment on the agency's proposed calculations.<sup>19</sup>

As a result, patients who are to be protected by the statute have a right to transparent access to the calculations used to arrive at the allowed amount for out-of-network emergency services, and a provider can obtain this information as a patient's authorized representative.<sup>20</sup> To the extent that a provider is not able to obtain these calculations, the Departments believe that the patients' ability to obtain and to potentially challenge the information through litigation or the appeals process creates adequate safeguards with respect to ACEP's concerns regarding health insurance issuer manipulation of UCR amounts. This provides sufficient protections, especially in light of the focus of section 2719A of the PHS Act on the protection of patients, rather than physicians. For all these reasons, the Departments believe that the methodology in the GOT regulations is sufficiently transparent and reasonable.

### *B. Creation of a Database or Use of a Publicly Available Database Is Problematic*

The creation and use of ACEP's proposed database on payments and charges would be problematic in a number of ways. The establishment and maintenance of a publicly available database would be time-consuming, would require contracting assistance, and would be costly and burdensome to maintain. Furthermore, there is no indication that such a database would

be a better barometer of UCR amounts than the current methodology used by group health plans and health insurance issuers.

ACEP's suggestion that the Departments mandate the use of an existing database (for example, FAIR Health) presents similar issues. As an initial matter, determining which existing database (if any) is appropriate for calculating UCR, and then monitoring the database, would be costly and time-consuming. And, as with ACEP's suggestion that the Departments create a database, there is no indication that a publicly available database would be a better barometer of UCR amounts than the current methodology used by group health plans and health insurance issuers.

Thus, the Departments concluded in the November 2015 final rule, and still maintain, that the existing GOT regulation provides a statutorily supportable, and also a more practical, and cost-effective approach for group health plans and health insurance issuers to determine the required minimum payment amounts. Further, the Departments did not have a mandate to require plans and issuers to use different databases for the purposes of implementing the Patient Protections statutory requirements from what they may currently use, and the Departments decline to mandate the use of one particular database in the limited context of this rulemaking. It is the Departments' view that it is appropriate to continue to reserve the determination of the relative merits of each database to the discretion of the states, insurers, and health plans.<sup>21</sup>

### **III. Conclusion**

The Departments believe that the November 2015 final rule provides a reasonable methodology to determine appropriate payments by group health plans and health insurance issuers for out-of-network emergency services, in light of the statutory language in section 2719A of the PHS Act and the totality of the comments received in response to the June 2010 IFR. The Departments also believe that the three prongs of the GOT regulation are sufficiently transparent. ACEP's proposal that the GOT regulation require the development of a database or utilization of a publicly available database to set UCR amounts would require the Departments to extend the scope of authority provided under section 2719A of the PHS Act to

<sup>21</sup> The website of the All Claims Payable Database Council lists 19 states with legislation enabling the collection of claims and databases. <https://www.apcdouncil.org/apcd-legislation-state>.

<sup>16</sup> See DOL Advisory Opinion 96-14A (July 31, 1996). See also FAQs about Affordable Care Act Implementation Part 31, Mental Health Parity Implementation, and Women's Health and Cancer Rights Act Implementation, available at <https://www.dol.gov/sites/default/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-31.pdf> and [https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQs-31\\_Final-4-20-16.pdf](https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQs-31_Final-4-20-16.pdf).

<sup>17</sup> 26 CFR 54.9815-2719(b); 29 CFR 2590.715-2719(b); 45 CFR 147.136(b). See also footnote 11.

<sup>18</sup> See Social Security Act Section 1848(b)(1).

<sup>19</sup> See id.

<sup>20</sup> See 29 CFR 2560.503-1(b)(4). See also 26 CFR 54.9815-2719(b)(2)(i), 29 CFR 2590.715-2719(b)(2)(i), and 45 CFR 147.136(b)(2)(i), requiring non-grandfathered group health plans and issuers to incorporate the internal claims and appeals processes set forth in 29 CFR 2560.503-1.

intrude on state authority and group health plan and health insurance issuer discretion; and even if the Departments were prepared to extend their authority in this manner, the establishment and maintenance of a database or the assessment, validation, and monitoring of a publicly available database would be costly and time-consuming. Further, there is no indication that such a database would provide a better method for determining UCR amounts than the methods group health plans and health insurance issuers currently use. The Departments therefore decline to adopt the suggestions of ACEP and other commenters that made similar suggestions regarding the GOT regulation.

#### IV. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501, *et seq.*).

**Kirsten B. Wielobob,**

*Deputy Commissioner for Services and Enforcement, Internal Revenue Service.*

Approved: April 25, 2018.

**David J. Kautter,**

*Assistant Secretary of the Treasury (Tax Policy).*

Approved: April 25, 2018.

Signed this 25th day of April 2018.

**Preston Rutledge,**

*Assistant Secretary, Employee Benefits Security Administration, Department of Labor.*

Dated: April 25, 2018.

**Seema Verma,**

*Administrator, Centers for Medicare & Medicaid Services.*

Dated: April 27, 2018.

**Alex M. Azar II,**

*Secretary, Department of Health and Human Services.*

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## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

#### 33 CFR Part 165

[Docket Number USCG-2018-0397]

RIN 1625-AA00

#### Safety Zone; Straits of Mackinac, Mackinaw City, MI

**AGENCY:** Coast Guard, DHS.

**ACTION:** Temporary final rule.

**SUMMARY:** The Coast Guard is establishing a temporary safety zone for navigable waters within a 500-yard radius of construction equipment vessels conducting operations in the Straits of Mackinac. The safety zone is needed to protect personnel, vessels, and the marine environment from potential hazards created by surveillance and repair work to electric utility cables that cross the Straits of Mackinac. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port Sault Sainte Marie or a designated representative.

**DATES:** This rule is effective from May 3, 2018 until October 30, 2018. It will be enforced with actual notice from April 30, 2018, until May 3, 2018.

**ADDRESSES:** To view documents mentioned in this preamble as being available in the docket, go to <http://www.regulations.gov>, type USCG-2018-0397 in the "SEARCH" box and click "SEARCH." Click on Open Docket Folder on the line associated with this rule.

**FOR FURTHER INFORMATION CONTACT:** If you have questions on this rule, call or email LTJG Sean V. Murphy, Sector Sault Sainte Marie Waterways Management Chief, U.S. Coast Guard; telephone 906-635-3319, email [ssmprevention@uscg.mil](mailto:ssmprevention@uscg.mil).

#### SUPPLEMENTARY INFORMATION:

##### I. Table of Abbreviations

CFR Code of Federal Regulations  
 DHS Department of Homeland Security  
 FR Federal Register  
 NPRM Notice of proposed rulemaking  
 § Section  
 U.S.C. United States Code  
 ROV Remotely Operated Underwater Vehicle

##### II. Background Information and Regulatory History

The Coast Guard is issuing this temporary rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the

Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency, for good cause, finds that those procedures are "impracticable, unnecessary, or contrary to the public interest." Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because visual imagery and repair of damage to the utility cables is imperative to further mitigate any risks to the environment and the public. Emergent conditions require immediate marine surveying of the area due to damage to utility cables in the Straits of Mackinac. It is impractical to publish an NPRM because of the urgent need to survey the utility cables damaged.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule would be impracticable because immediate action is needed to obtain visual imagery of damage to the utility cables in order to successfully effect repairs and further mitigate any risks to the environment and the public.

##### III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 33 U.S.C. 1231. The Captain of the Port Sault Sainte Marie (COTP) has determined that construction vessels operating in the Straits of Mackinac, will be a safety and navigation concern for any vessel within a 500-yard radius of the operations. This rule is needed to protect personnel, vessels, and the marine environment in the navigable waters within the safety zone while the operations are ongoing.

##### IV. Discussion of the Rule

This rule establishes a safety zone from April 30, 2018 until October 30, 2018. The safety zone will cover all navigable waters within 500 yards of construction equipment vessel working and surveying damaged utility cables in the Straits of Mackinac. The duration of the zone is intended to protect personnel, vessels, and the marine environment in these navigable waters while operations are ongoing. The zone will be enforced at various times throughout this period. Local Broadcast Notice to mariners, via VHF-FM marine channel 16, will notify mariners when the construction vessels are conducting operations and the zone is being enforced. No vessel or person will be permitted to enter the safety zone