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.


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

§ 102.50 Crabmeat.

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


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

   § 102.50 Crabmeat.
   * * * * *

   Scientific name of crab          Common or usual name of crabmeat

   Chionoecetes opilio,            Snow crabmeat.
   Chionoecetes tanneri,           Korean variety crabmeat
   Chionoecetes bairdi,            or Kegani crabmeat.
   and Chionoecetes angulus,
   Enimarcus isenbeckii .........  Golden King crabmeat.
   Lithodes aequispinus ......    King crabmeat or
   Paralithodes brevipes ......  Hanasaki crabmeat.
   Paralithodes camtschaticus and  King crabmeat.
   Paralithodes platypus.


   Leslie Kux,
   Associate Commissioner for Policy.
   [FR Doc. 2018–09371 Filed 5–2–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 54

[TD 9744]

RIN 1545–B145, 1545–B350, 1545–B62, 1545–B57

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), as 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 1 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 providers.” 2 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 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 “maximum amount on which payment is based for covered health care services”). 3 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)(ii) of the PHS Act applies to cost sharing “expressed as a copayment amount or coinsurance rate.” 4

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

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1 See 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 and obstetrical and gynecological care. This document does not address those aspects of section 2719A of the PHS Act.

2 See section 2719A(b)(1)(B) of the PHS Act.


4 See PPACA section 1302(c)(3)(B). See also 80 FR 72192, 72212–13 (Nov. 18, 2015).
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). ACP’s August 3, 2010 comment letter 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 paid encounter data to be used 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 database, if included in the regulation, might improve the transparency. Insurers know that emergency physicians will see everyone who comes to the ED due to EMTALA, and many leverage that fact to impose extremely low reimbursement rates. We believe that this concern is addressed by our requirement that the amount be the greatest of the three amounts specified in [the GOT regulation].”9

B. Other Guidance

In response to concerns about transparency with respect to the second prong of the GOT regulation raised by ACP 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

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5 75 FR at 37194 (footnote omitted). For the interim final regulation text, see 75 FR at 37233, 37234, and 37236.

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

7 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.

8 The final regulations incorporated guidance that had been provided in FAQs about Affordable Care Act Implementation (Part I), Q15, available at www.dol.gov/esa/faps/faq-aca.html and https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementaion_facts.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).

9 80 FR 72192, 72213 (Nov. 18, 2015).
and Cancer Rights Act Implementation, which addressed, in part, the GOT regulation. 10 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. 11 In addition, the Department of Labor claims procedure regulations, as well as the internal claims and appeals and external review requirements 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. 12

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. 13 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. 14 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 “the 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 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.’” 15 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

13 See https://www.acep.org/Legislation-and-Advocacy/Regulatory/ACEPRegHHS_051216/.
14 See https://www.acep.org/Legislation-and-Advocacy/Regulatory/ACEPRegHHS_051216/.
15 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 issuers 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.16

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.17

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.18 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.19

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.20 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.21

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

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17 26 CFR 54.9815–2719(b); 29 CFR 2590.715–2719(b); 45 CFR 147.136(b). See also footnote 11.

18 See Social Security Act Section 1848(b)(1).

19 See id.


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.


Seema Verma,
Administrator, Centers for Medicare & Medicaid Services.


Alex M. Azar II,
Secretary, Department of Health and Human Services.

[FR Doc. 2018–09369 Filed 4–30–18; 4:15 pm]