DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 425

[CMS–1702—IFC]

RIN 0938–AT51

Medicare Program; Medicare Shared Savings Program: Extreme and Uncontrollable Circumstances Policies for Performance Year 2017

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Interim final rule with comment period.

SUMMARY: This interim final rule with comment period establishes policies for assessing the financial and quality performance of Medicare Shared Savings Program (Shared Savings Program) Accountable Care Organizations (ACOs) affected by extreme and uncontrollable circumstances during performance year 2017, including the applicable quality reporting period for the performance year. Under the Shared Savings Program, providers of services and suppliers that participate in ACOs continue to receive traditional Medicare fee-for-service (FFS) payments under Parts A and B, but the ACO may be eligible to receive a shared savings payment if it meets specified quality and savings requirements. ACOs in performance-based risk agreements may also share in losses. This interim final rule with comment period establishes extreme and uncontrollable circumstances policies for the Shared Savings Program that will apply to ACOs subject to extreme and uncontrollable events, such as Hurricanes Harvey, Irma, and Maria, and the California wildfires, effective for performance year 2017, including the applicable quality data reporting period for the performance year.

DATES:

Effective date: These regulations are effective on January 20, 2018.

Comment date: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on February 20, 2018.

ADDRESSES: In commenting, please refer to file code CMS–1702–IFC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission. You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *www.regulations.gov.* Follow the instructions for ''submitting a comment.''

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1702–IFC, P.O. Box 8016, Baltimore, MD 21244–8013. Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1702–IFC, Mail stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to either of the following addresses:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue SW, Washington, DC 20201. (Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850. If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786–7195 in advance to schedule your arrival with one of our staff members. Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period. For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Sabrina Ahmed, (410) 786–7499.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: *http://regulations.gov.* Follow the search instructions on that website to view public comments.

I. Background

Stakeholders representing Medicare Shared Savings Program (Shared Savings Program) Accountable Care Organizations (ACOs) located in the geographic areas impacted by Hurricanes Harvey, Irma, and Maria and the California wildfires have reported significant impacts on healthcare provider operations and on area infrastructure. (For more detailed information, see the interim final rule with comment period titled Medicare Program; Quality Payment Program: Extreme and Uncontrollable Circumstance Policy for the Transition Year that appeared in the **Federal Register** on November 16, 2017 (hereinafter referred to as the Quality Payment Program IFC) (82 FR 53568 and 53895). For example, Hurricane Maria devastated Puerto Rico on September 20, 2017. Stakeholders located in Puerto Rico report that while federal and local agencies have been working around the clock to restore infrastructure in Puerto Rico, local communication systems are still not fully functioning, some residents do not have water services, and many residents do not have access to electric power. Under such circumstances, healthcare providers report that their main focus is to manage chronically ill patients; provide essential services such as dialysis, chemotherapy, and blood transfusions; deal with trauma; and dispense maintenance medications, including insulin. Many healthcare providers in Puerto Rico have been unable to reopen their offices not only because they lack power and water, but also because access to fuel for operating alternate power generators has been limited.

In addition, other stakeholders report that the loss of infrastructure has significantly affected the utilization and cost of services furnished to the Medicare beneficiaries they serve. For example, stakeholders representing ACOs in Florida indicate there has been a significant increase in emergency department services, hospitalizations, and skilled nursing facility (SNF) admissions because of Hurricane Irma. They believe that the increased numbers

of medical services being furnished in their geographic areas is a direct result of hurricane-related factors affecting healthcare providers that are beyond their control. Stakeholders report that, in some cases, beneficiaries located in hurricane-affected areas who are being treated for chronic conditions, such as diabetes, have limited access to their primary clinicians and have not been able to obtain timely refills for their prescribed medications, resulting in an increased volume of hospital and SNF admissions, as well as increased volumes of other medical services. Stakeholders suggest that beneficiaries in affected areas are more likely to be admitted to hospitals and SNFs, and to require other additional medical services when basic infrastructure has been damaged, such as when beneficiaries are unable to utilize ventilators or other medically necessary equipment at home or in another less intensive setting because of widespread electrical outages. Further, ACOs located in affected areas report that ACO providers/suppliers, including hospitals and SNFs, are struggling to help beneficiaries meet their post-discharge needs, including for housing, family support, and personal care. Stakeholders report that as a result, in some cases, patients may have remained in inpatient facilities due to the lack of appropriate post-discharge services.

Under the Shared Savings Program, ACOs that successfully meet quality and savings requirements can share a percentage of the achieved savings with Medicare. Eligible ACOs share in savings only if they meet both the quality performance standards and generate shareable savings (see §§ 425.604(a)(7), (b) and (c); 425.606(a)(7), (b) and (c); and 425.610(a)(7), (b) and (c)). ACOs participating in a two-sided risk model are required to share losses with the Medicare program when expenditures over the benchmark exceed the minimum loss rate (see §§ 425.606(b), (f) and (g); and 425.610(b), (f) and (g)). ACOs have expressed concerns that disaster-related effects on their ACO participants and assigned beneficiary population could affect their ability to successfully meet the quality performance standards, and in the case of ACOs under performance-based risk, to avoid shared losses. Stakeholders are concerned about the impact on ACO performance results when comparing performance year expenditures that reflect disaster-related spikes in utilization and costs of medical services against historical benchmarks that do not include the costs of a disaster. For instance, in light of the challenges being faced by healthcare providers in Puerto Rico, stakeholders estimate that it might take ACO participants in Puerto Rico from 3 to 6 months, at a minimum, to comply with quality measures reporting requirements for performance year 2017. Stakeholders are also concerned that ACOs and ACO participants affected by disasters could be unfairly assessed for performance year 2017 based on the quality and claims data that would be available during financial reconciliation for performance year 2017. For example, stakeholders have expressed the following concerns:

- There could be very limited ability to obtain beneficiary survey responses to the Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey through phone calls and mailings. Further, the widespread devastation of infrastructure and the impact on healthcare providers would likely adversely impact beneficiary access to care and beneficiary ratings of services, which could negatively affect results on the CAHPS survey measures.
- ACO quality performance scores could be adversely affected by a limited ability to furnish and/or submit claims for cancer screening services, diabetic eye exams, or other preventive services. This would impact ACOs' quality performance scores because higher rates are better for many of the quality measures, such as ACO–19 Colorectal Cancer Screening or ACO–20 Breast Cancer Screening.
- There could be a high number of unplanned hospital and SNF admissions, and high use of emergency room services due to multiple disaster-related factors, such as beneficiary exposure to contagious illnesses and limited access to medicines for beneficiaries with chronic conditions. This could significantly impact ACOs' quality performance scores because lower rates of admissions are better for measures, such as ACO–35 SNF 30-day All-Cause Readmission Measure or ACO–36 All-Cause Unplanned Admissions for Patients with Diabetes.
- The impact of the disasters on an ACO's financial performance could be unpredictable as a result of the increase in utilization and cost of services furnished to the Medicare beneficiaries it serves. In some cases, ACO participants might be unable to coordinate care because of migration of patient populations leaving the impacted areas. Stakeholders have expressed concerns that existing Track 2 and Track 3 ACOs may be unable to remain in a two-sided risk track if they are held fully accountable for repaying shared losses associated with these disasters. We also note that our experience with the Shared Savings Program has been that the majority of ACOs that owe shared losses subsequently terminate their agreements.

These stakeholders further suggest that in the future providers and suppliers could be reluctant to participate in the Shared Savings Program under a two-sided risk model because of concerns that ACOs participating under a two-sided risk model could be required to share losses with the Medicare program for expenditures resulting from extreme and uncontrollable circumstances.

Disasters may have several possible effects on our ability to measure ACO quality performance. For instance, displacement of beneficiaries may make it difficult for ACOs to access medical record data required for quality reporting, as well as reduce the beneficiary response rate on survey measures. Further, for practices damaged by a disaster, the medical records needed for quality reporting may be inaccessible.

We also believe that disasters may affect the infrastructure of ACO participants, ACO providers/suppliers, and potentially the ACO legal entity itself, thereby disrupting routine operations related to their participation in the Shared Savings Program and achievement of program goals. The effects of a disaster could include challenges in communication between the ACO and its participating providers and suppliers and in implementation of and participation in programmatic activities. These factors could jeopardize an ACO's ability to remain in the program, particularly for ACOs that have accepted performance-based risk under Tracks 2 and 3. Stakeholders have requested that we develop policies under the Shared Savings Program to recognize the impact of extreme and uncontrollable circumstances on ACO quality and financial performance.

II. Provisions of the Interim Final Rule

A. Shared Savings Program Extreme and Uncontrollable Circumstances Policies for Performance Year 2017

We agree with stakeholders that the financial and quality performance of ACOs located in areas subject to extreme and uncontrollable circumstances could be significantly and adversely affected. We also agree that due to the widespread disruptions that have occurred during 2017 in areas affected by Hurricanes Harvey, Irma, and Maria, and the California wildfires, new policies are warranted for assessing

quality and financial performance of Shared Savings Program ACOs in the affected areas. We believe it is appropriate to adopt policies to address stakeholder concerns that displacement of beneficiaries may make it difficult for ACOs to access medical record data required for quality reporting, and might reduce the beneficiary response rate on survey measures. In addition, medical records needed for quality reporting may be inaccessible. We also believe it is appropriate to adopt policies to address stakeholders' concerns that ACOs might be held responsible for sharing losses with the Medicare program resulting from catastrophic events outside the ACO's control given the increase in utilization, migration of patient populations leaving the impacted areas, and the mandatory use of natural disaster payment modifiers making it difficult to identify whether a claim would otherwise have been denied under normal Medicare fee-for-service (FFS) rules.

Under the Shared Savings Program, we do not currently have policies for addressing ACO quality performance scoring and the determination of the shared losses owed by ACOs participating under performance-based risk tracks in the event of an extreme or uncontrollable circumstance. In the Quality Payment Program IFC (82 FR 53895), we established an automatic policy to address extreme and uncontrollable circumstances, including Hurricanes Harvey, Irma, and Maria, for the Merit-based Incentive Payment System (MIPS) for the 2017 performance year. (The specific regions identified as being affected by Hurricanes Harvey, Irma, and Maria for the 2017 MIPS performance year are provided in detail in section III.B.1.e. of the Quality Payment Program IFC (82 FR 53898)). In the Quality Payment Program IFC, we stated that should additional extreme and uncontrollable circumstances arise for the 2017 MIPS performance period that trigger the automatic extreme and uncontrollable circumstance policy under the Quality Payment Program, we would communicate that information through routine communication channels, including but not limited to issuing program memoranda, emails to stakeholders, and notices on the Quality Payment Program website, *qpp.cms.gov* (82 FR 53897). For example, we recently issued guidance to stakeholders indicating that the MIPS Extreme and Uncontrollable Circumstance Policy also applies to MIPS eligible clinicians affected by the California wildfires (see *https://www.cms.gov/Medicare/Quality-Payment-Program/Resource-Library/Interim-Final-Rule-with-Comment-fact-sheet.pdf*).

We believe it is also appropriate to establish automatic extreme and uncontrollable circumstances policies under the Shared Savings Program for performance year 2017 due to the urgency of providing relief to Shared Savings Program ACOs impacted by Hurricanes Harvey, Irma, and Maria, and the California wildfires, because their quality scores could be adversely affected by these disasters and some ACOs could be at risk for additional shared losses due to the costs associated with these extreme and uncontrollable events. Therefore, given the broad impact of the three hurricanes and the wildfires, and to address any additional extreme and uncontrollable circumstances that may arise during 2017 or the quality data reporting period for the performance year, we are establishing the policies described below for the Shared Savings Program for performance year 2017.

For program clarity and to reduce unnecessary burdens on affected ACOs, we are aligning the automatic extreme and uncontrollable circumstances policies under the Shared Savings Program with the policy established under the Quality Payment Program. Specifically, the Shared Savings Program extreme and uncontrollable circumstances policies will apply when we determine that an event qualifies as an automatic triggering event under the Quality Payment Program. We will use the determination of an extreme and uncontrollable circumstance under the Quality Payment Program, including the identification of affected geographic areas and applicable time periods, for purposes of determining the applicability of the extreme and uncontrollable circumstances policies with respect to both financial performance and quality reporting under the Shared Savings Program. These policies will also apply with respect to the determination of the ACO's quality performance in the event that an extreme and uncontrollable event occurs during the applicable quality data reporting period for performance year 2017 and the reporting period is not extended. We believe it is appropriate to extend these policies to encompass the quality reporting period, unless the reporting period is extended, because we would not have the quality data necessary to measure an ACO's quality performance for 2017 if the ACO were unable to submit its quality data as a result of a disaster occurring during the submission window. For example, if an extreme and uncontrollable event were to occur in February 2018, which is during the quality data reporting period for performance year 2017 that is currently scheduled to end on March 16, 2018 at 8 p.m. eastern daylight time, then the extreme and uncontrollable circumstances policies would apply for quality data reporting for performance year 2017, if the reporting period is not extended. We do not believe it is appropriate to extend this policy to encompass the quality data reporting period if the reporting period is extended because affected ACOs would have an additional opportunity to submit their quality data, enabling us to measure their quality performance in 2017. However, we note that, because a disaster that occurs after the end of the performance year would have no impact on the determination of an ACO's financial performance for performance year 2017, we will make no adjustment to shared losses in the event an extreme or uncontrollable event occurs during the quality data reporting period.

1. Determination of Quality Performance Scores for ACOs in Affected Areas

ACOs and their ACO participants and ACO providers/suppliers are frequently located across several different geographic regions or localities, serving a mix of beneficiaries who may be differentially impacted by hurricanes, wildfires, or other triggering events. Therefore, we need to establish a policy for determining when an ACO, which may have ACO participants and ACO providers/suppliers located in multiple geographic areas, should qualify for the automatic extreme and uncontrollable circumstance policies for the determination of quality performance. We will determine whether an ACO has been affected by an extreme and uncontrollable circumstance by determining whether 20 percent or more of the ACO's assigned beneficiaries resided in counties designated as an emergency declared area in performance year 2017, as determined under the Quality Payment Program as discussed in section III.B.1.e. of the Quality Payment Program IFC (82 FR 53898) or the ACO's legal entity is located in such an area. An ACO's legal entity location is based on the address on file for the ACO in CMS' ACO application and management system. We are using 20 percent of the ACO's assigned beneficiary population as the minimum threshold to establish an ACO's eligibility for the policies regarding quality reporting and quality performance scoring included in this interim final rule with comment period because we believe the 20 percent threshold provides a reasonable way to

identify ACOs whose quality performance may have been adversely affected by an extreme or uncontrollable circumstance, while excluding ACOs whose performance would not likely be significantly affected. The 20 percent threshold was selected to account for the effect of an extreme or uncontrollable circumstance on an ACO that has the minimum number of assigned beneficiaries to be eligible for the program (5,000 beneficiaries), and in consideration of the average total number of unique beneficiaries for whom quality information is required to be reported in the combined CAHPS survey sample (860 beneficiaries) and the CMS web interface sample (approximately 3,500 beneficiaries). (There may be some overlap between the CAHPS sample and the CMS web interface sample.) Therefore, we estimated that an ACO with an assigned population of 5,000 beneficiaries typically would be required to report quality information on a total of 4,000 beneficiaries. Thus, we believe the 20 percent threshold ensures that an ACO with the minimum number of assigned beneficiaries would have an adequate number of beneficiaries across the CAHPS and CMS web interface samples in order to fully report on these measures. Of the ACOs we have estimated will be impacted by the disasters in 2017, 92 percent have more than 20 percent of their assigned beneficiaries residing in emergency declared areas. However, we also understand that some ACOs that have fewer than 20 percent of their assigned beneficiaries residing in affected areas have a legal entity that is located in an emergency declared area. Consequently, their ability to quality report may be equally impacted since the ACO legal entity may be unable to collect the information from the ACO participants or experience infrastructure issues related to capturing, organizing and reporting the data to CMS. If less than 20 percent of the ACO's assigned beneficiaries reside in an affected area and the ACO's legal entity is not located in a county designated as an affected area, then we believe that there is unlikely to be a significant impact upon the ACO's ability to report or on the representativeness of the quality performance score that is determined for the ACO.

We will determine what percentage of the ACO's performance year assigned population was affected by a disaster based on the final list of beneficiaries assigned to the ACO for the performance year. Although beneficiaries are assigned to ACOs under Track 1 and Track 2 based on preliminary prospective assignment with retrospective reconciliation after the end of the performance year, these ACOs will be able to use their quarterly assignment lists, which include beneficiaries' counties of residence, for early insight into whether they are likely to meet the 20 percent threshold. We have used preliminary information on beneficiary assignment for the 2017 performance year to estimate the number of ACOs that were affected by the hurricanes and the California wildfires in 2017. We estimate that 105 of the 480 ACOs (approximately 22 percent) would meet the minimum threshold of having 20 percent or more of their assigned beneficiaries residing in an area designated as impacted by Hurricanes Harvey, Irma, and Maria, and the California wildfires or have their legal entity located in one of these areas.

For purposes of determining quality performance scoring for performance year 2017, if 20 percent or more of an ACO's assigned beneficiaries reside in an area impacted by the disaster or the ACO's legal entity is located in such an area, the ACO's minimum quality score will be set to equal the mean Shared Savings Program ACO quality score for all ACOs for performance year 2017. We are setting the minimum quality score equal to the mean quality score for all Shared Savings Program ACOs nationwide, because the mean reflects the full range of quality performance across all ACOs in the Shared Savings Program. More specifically, the mean ACO quality score is equal to the combined ACO quality score for all ACOs meeting the quality performance standard for the performance year divided by the total number of ACOs meeting the quality performance standard for the performance year. To illustrate, we note that the mean Shared Savings Program ACO quality performance score for all participating ACOs for performance year 2016 was approximately 95 percent. In the event an affected ACO is able to complete quality reporting for performance year 2017, and the ACO's calculated quality score is higher than the mean Shared Savings Program ACO quality score, then we would apply the higher score.

In earlier rulemaking, we finalized a policy under which ACOs that demonstrate quality improvement on established quality measures from year-to-year will be eligible for up to 4 bonus points per domain (79 FR 67927 through 67931, § 425.502(e)(4)). To earn bonus points, an ACO must demonstrate a net improvement in performance on measures within a domain. If an ACO is not able to complete quality reporting for performance year 2017, it will not be possible for us to assess the ACO's improvement on established quality measures since performance year 2016. Therefore, if an ACO receives a quality score based on the mean quality score, the ACO is not eligible for bonus points awarded based on quality improvement.

We believe it is appropriate to adjust the quality performance scores for ACOs in affected areas because we anticipate that such ACOs will likely be unable to collect or report the necessary information to CMS as a result of the extreme and uncontrollable circumstance, and/or the ACO's quality performance score will be significantly and adversely affected. Section 1899(b)(3)(C) of the Act gives us the authority to establish the quality performance standards used to assess the quality of care furnished by ACO. Accordingly, we are modifying the quality performance standard specified under § 425.502 by amending paragraph (e)(4) and adding a new paragraph (f) to address potential adjustments to the quality performance score for performance year 2017 of ACOs determined to be affected by extreme and uncontrollable circumstances. For performance year 2017, including the applicable quality data reporting period for the performance year if the reporting period is not extended, in the event that we determine that 20 percent or more of an ACO's final list of assigned beneficiaries for the performance year, as determined under subpart E of the Shared Savings Program regulations, reside in an area that is affected by an extreme and uncontrollable circumstance as determined under the Quality Payment Program, or that the ACO's legal entity is located in such an area, we will use the following approach to calculate the ACO's quality performance score instead of the methodology specified in § 425.502(a) through (e).

- The ACO's minimum quality score will be set to equal the mean Shared Savings Program ACO quality score for performance year 2017.
- If the ACO is able to completely and accurately report all quality measures, we will use the higher of the ACO's quality score or the mean Shared Savings Program ACO quality score.
- If the ACO receives a quality score based on the mean, the ACO is not eligible for bonus points awarded based on quality improvement.

We will apply determinations made under the Quality Payment Program with respect to whether an extreme and uncontrollable circumstance has occurred and the affected areas. We

have sole discretion to determine the time period during which an extreme and uncontrollable circumstance occurred, the percentage of the ACO's assigned beneficiaries residing in the affected areas, and the location of the ACO legal entity.

For purposes of the MIPS APM scoring standard, MIPS eligible clinicians in Medicare Shared Savings Program ACOs that do not completely report quality for 2017; and therefore, receive the mean ACO quality score under the Shared Savings Program would receive a score of zero percent in the MIPS quality performance category. However, these MIPS eligible clinicians would receive a score of 100 percent in the improvement activities (IAs) performance category, which would be sufficient for them to receive a 2017 MIPS final score above the performance threshold. This would result in at least a slight positive MIPS payment adjustment in 2019. Additionally, if the ACO participants are able to report advancing care information (ACI), the MIPS eligible clinicians in the ACO will receive an ACI performance category score under the APM scoring standard which would further increase their final score under MIPS.

2. Mitigating Shared Losses for ACOs Participating in a Performance-Based Risk Track

In addition, we are modifying the payment methodology under Tracks 2 and 3 established under the authority of section 1899(i) of the Act to mitigate shared losses owed by ACOs affected by extreme and uncontrollable circumstances during performance year 2017. Under this policy, we will reduce the ACO's shared losses, if any, determined to be owed under the existing methodology for calculating shared losses in part 425, subpart G, of the regulations by an amount determined by multiplying the shared losses by two factors: (1) The percentage of the total months in the performance year affected by an extreme and uncontrollable circumstance; and (2) the percentage of the ACO's assigned beneficiaries who reside in an area affected by an extreme and uncontrollable circumstance. We will determine the percentage of the ACO's performance year assigned beneficiary population that was affected by the disaster based on the final list of beneficiaries assigned to the ACO for the performance year. For example, assume that an ACO is determined to owe shared losses of $100,000 for performance year 2017, a disaster was declared for October through December during the performance year, and 25 percent of the ACO's assigned beneficiaries reside in the disaster area. In this scenario, we would adjust the ACO's losses in the following manner:

$$\$100{,}000 - (\$100{,}000 \times 0.25 \times 0.25) = \$100{,}000 - \$6{,}250 = \$93{,}750.$$

We believe it is appropriate to adopt this policy to address stakeholders' concerns that ACOs could be held responsible for sharing losses with the Medicare program resulting from catastrophic events outside the ACO's control given the increase in utilization, difficulty of coordinating care for patient populations leaving the impacted areas, and the mandatory use of natural disaster payment modifiers making it difficult to identify whether a claim would otherwise have been denied under normal Medicare FFS rules. Absent this relief, we believe ACOs that are currently participating in Tracks 2 and 3 may reconsider whether they are able to continue their participation in the Shared Savings Program under a performance-based risk track. The approach we are adopting in this interim final rule with comment period balances the need to offer relief to affected ACOs with the need to continue to hold those ACOs accountable for losses incurred during the months in which there was no applicable disaster declaration and for the assigned beneficiary population that was outside the area affected by the disaster. We also note that these policies do not change the status of Track 2 or Track 3 of the Shared Savings Program as an Advanced Alternative Payment Model (APM) for purposes of the Quality Payment Program, or prevent an eligible clinician in a performance-based risk ACO from becoming a Qualifying APM Participant for purposes of the APM incentive under the Quality Payment Program.

We also explored an alternative approach for mitigating the potential losses for ACOs in performance-based risk tracks that are affected by extreme and uncontrollable circumstances. Under this approach, we would remove claims for services furnished to assigned beneficiaries in the impacted areas by an ACO participant that are submitted with a natural disaster modifier before calculating financial performance. However, we believe that this alternative approach could, for some affected ACOs, result in the exclusion of a significant amount of their total claims at financial reconciliation, making it very difficult to measure the ACOs' financial performance.

We also want to emphasize that all ACOs will continue to be entitled to share in any savings they may achieve for performance year 2017. The calculation of savings and the determination of shared savings payment amounts will not be affected by the policies to address extreme and uncontrollable circumstances. ACOs in all three tracks of the program will receive shared savings payments, if any, as determined under part 425, subpart G.

We also considered the possible impact of extreme and uncontrollable circumstances on an ACO's expenditures for purposes of determining the benchmark (§§ 425.602 and 425.603). The additional costs incurred as a result of an extreme or uncontrollable circumstance would likely impact the benchmark determined for the ACO's subsequent agreement period in the Shared Savings Program, as performance years of the current agreement period become the historical benchmark years for the subsequent agreement period. We currently believe that the increase in expenditures for a particular calendar year would result in a higher benchmark value when the same calendar year is used to determine the ACO's historical benchmark, and in calculating adjustments to the rebased benchmark based on regional FFS expenditures (§ 425.603). We believe that any effect of including these additional expenditures in determining the ACO's benchmark for the subsequent agreement period could be mitigated somewhat because the ACO's expenditures during the three base years included in the benchmark are weighted equally, and regional expenditures would also increase as a result of the disaster. Therefore, we anticipate the effect on the regional adjustment under § 425.603(c)(9) would be minimal. Although we are not modifying the program's historical benchmark methodology in this interim final rule with comment period, we plan to observe the impact of the 2017 hurricanes and wildfires on ACO expenditures, and may revisit the need to make adjustments to the methodology for calculating the benchmark in future rulemaking.

To exercise our authority under section 1899(i)(3) of the Act to use other payment models, we must demonstrate that the payment model— (1) '' . . . does not result in spending more for such ACO for such beneficiaries than would otherwise be expended . . . if the model were not implemented. . . .'' and (2) ''will improve the quality and efficiency of items and services furnished under'' Medicare. In assessing the impacts of the policy for mitigating shared losses for Track 2 and Track 3 ACOs affected by extreme and

uncontrollable circumstances in 2017, we considered: The impact of the potential loss of participation in the program by ACOs affected by disasters should we not implement the policy described in this interim final rule with comment period, and the anticipated minimal impact of adjusting losses for ACOs affected by disasters, as described in the regulatory impact statement. On the basis of this assessment, we believe incorporating this extreme and uncontrollable circumstances policy into the payment methodologies for Tracks 2 and 3 would meet the requirements of section 1899(i) of the Act by not increasing expenditures above the costs that would be incurred under the statutory payment methodology under section 1899(d) of the Act and by encouraging affected ACOs to remain in the program, which we believe will increase the quality and efficiency of the items and services furnished to the beneficiaries they serve. We also note that to the extent the policies in this interim final rule with comment constitute a change to the Shared Savings Program payment methodology for 2017 after the start of the performance year, we believe that, consistent with section 1871(e)(1)(A)(ii) of the Act, and for reasons discussed in section III of this interim final rule with comment period, it would be contrary to the public interest not to adjust the shared losses calculated for ACOs in Tracks 2 and 3 to reflect the impact of the extreme and uncontrollable circumstances during 2017.

We invite comments on the policies being finalized in this interim final rule with comment period for performance year 2017, including the applicable quality data reporting period for performance year 2017 under the Shared Savings Program. We believe these automatic extreme and uncontrollable circumstance policies will reduce burden and financial uncertainty for ACOs, ACO participants, and ACO providers/suppliers affected by catastrophes, including ACOs affected by Hurricanes Harvey, Irma, and Maria, and the California wildfires, and will also align with existing Medicare policies under the Quality Payment Program for 2017.

We note that in future rulemaking, we intend to propose permanent policies under the Shared Savings Program to address extreme and uncontrollable circumstances in future performance years. Therefore, we also invite public comment on policies and issues that we should consider when developing proposals for these permanent policies.

We also welcome comments on how to address the impact of extreme and uncontrollable events on historical benchmark calculations, which we will consider in developing any future proposals. In particular, we seek comments as to whether and how the historical benchmark should be adjusted to reflect extreme and uncontrollable events that occur during a benchmark year, how to establish the threshold for determining whether a significant change in expenditures occurred, whether and how to account for changes in expenditures that have an aggregate positive or negative impact on the historical benchmark, and whether and how to reweight the benchmark years when calculating the historical benchmark if one or more benchmark years is impacted by an extreme and uncontrollable event.

III. Waiver of Proposed Rulemaking

Under 5 U.S.C. 553(b) of the Administrative Procedure Act (APA), the agency is required to publish a notice of the proposed rule in the **Federal Register** before the provisions of a rule take effect. Similarly, section 1871(b)(1) of the Act requires the Secretary to provide for notice of the proposed rule in the **Federal Register** and provide a period of not less than 60 days for public comment. Section 553(b)(B) of the APA provides for exceptions from the notice and comment requirements; in cases in which these exceptions apply, section 1871(b)(2)(C) of the Act provides for exceptions from the notice and 60-day comment period requirements of the Act as well. Section 553(b)(B) of the APA and section 1871(b)(2)(C) of the Act authorize an agency to dispense with normal rulemaking requirements for good cause if the agency makes a finding that the notice and comment process is impracticable, unnecessary, or contrary to the public interest.

We find that there is good cause to waive the notice and comment requirements under sections 553(b)(B) of the APA and section 1871(b)(2)(C) of the Act due to the impact of the recent disasters, as described in section I of this interim final rule with comment period, and the need to provide relief to impacted Shared Savings Program ACOs, ACO participants, and ACO providers/suppliers. Based on the size and scale of the destruction and displacement caused by these disasters in the affected regions, we believe it is likely that some ACOs and their ACO participants and ACO providers/suppliers have been significantly adversely affected by these events. It is possible that some ACO providers/suppliers may lack access to their EHR technology or other clinical data they would need in order to submit quality data for the 2017 performance period. Undertaking notice-and-comment rulemaking would not provide certainty for ACOs that must prepare now for quality reporting for performance year 2017, which begins on January 22, 2018. Moreover, there is no certainty that a final rule could be issued and in effect before the end of the quality reporting period for performance year 2017 on March 16, 2018. Absent this certainty, the prudent action for impacted ACOs would be to direct their attention and resources to attempt to report quality data for performance year 2017.

We believe it is likely that despite this effort, many affected ACOs would be unable to completely, accurately, and timely report given the lack of clinical information and infrastructure as a result of the disasters. This would result in unnecessary burden to impacted ACOs and their ACO participants and ACO providers/suppliers in the event a final rule is issued during or after the quality data submission period, and the ACO would have been afforded relief under the policies included in the final rule. Further, absent this certainty, ACOs participating under Tracks 2 and 3 that are located in disaster areas and that have experienced increased utilization would be concerned about being at risk for shared losses and would likely direct their attention and resources to contingency planning activities to develop options for offsetting the potential additional costs. These ACOs may also reconsider whether they are able to continue to their participation in the Shared Savings Program in a performance-based risk track. We believe it is also possible that potential ACO applicants could be reluctant to initiate the necessary advance planning and investments required to develop the capability to participate under a two-sided risk model during future performance years if they believe that we would be hesitant to provide similar flexibility in the event of future disasters, such that they may be at risk for losses resulting from circumstances beyond their control. Consequently, we believe it is in the public interest to adopt these interim final policies to provide relief to affected ACOs and their ACO participants and ACO providers/suppliers by mitigating the negative effects of the disasters during performance year 2017 on their quality and financial performance under the Shared Savings Program and allowing them to direct their resources toward caring for their patients and repairing structural damage to facilities.

We find that it would be impracticable and contrary to the public interest to undergo notice and comment procedures before finalizing, on an interim basis with an opportunity for public comment, policies under the Shared Savings Program to address extreme and uncontrollable circumstances that impact an entire region or locale in performance year 2017, including the applicable quality data reporting period. Therefore, we find good cause to waive the notice of proposed rulemaking as provided under section 553(b)(B) of the APA and section 1871(b)(2)(C) of the Act and to issue this interim final rule with an opportunity for public comment. We are providing a 60-day public comment period as specified in the **DATES** section of this document.

IV. Collection of Information Requirements

As stated in section 3022 of the Patient Protection and Affordable Care Act, Chapter 35 of title 44, United States Code, shall not apply to the Shared Savings Program. However, we note that this document does not impose any new information collection requirements (that is, reporting, recordkeeping, or third-party disclosure requirements).

V. Regulatory Impact Statement

These policies for addressing extreme and uncontrollable circumstances are unlikely to have a significant economic impact on the Shared Savings Program. We estimated the impact of these policies by simulating their effect on actual 2016 financial and quality performance results, the most recent available reconciled financial and quality results, for the ACOs currently participating in the program that are potentially impacted by these policies. The total increase in shared savings payments and total reduction in shared loss payments anticipated for ACOs impacted by the policies in this rule in 2017 is estimated to be approximately $3.5 million in total (which would round to zero assuming precision to the nearest $10 million). This interim final rule is not subject to the requirements of Executive Order 13771 because it is expected to result in no more than de minimis costs.

VI. Response to Public Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all public comments we receive by the date and time specified in the **DATES** section of this document, and, when we proceed with a subsequent document, we will respond to the public comments in the preamble to that document.

List of Subjects in 42 CFR Part 425

Administrative practice and procedure, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR part 425 as set forth below:

PART 425—MEDICARE SHARED SAVINGS PROGRAM

■ 1. The authority for part 425 continues to read as follows:

Authority: Secs. 1102, 1106, 1871, and 1899 of the Social Security Act (42 U.S.C. 1302, 1306, 1395hh, and 1395jjj).

■ 2. Amend § 425.502 by adding paragraphs (e)(4)(vi) and (f) to read as follows:

§ 425.502 Calculating the ACO quality performance score.

* * * * *

(e) * * *

(4) * * *

(vi) For performance year 2017, if an ACO receives the mean Shared Savings Program ACO quality score based on the extreme and uncontrollable circumstances policies in paragraph (f) of this section, the ACO is not eligible for bonus points awarded based on quality improvement.

(f) *Extreme and uncontrollable circumstances.* For performance year 2017, including the applicable quality data reporting period for the performance year if the quality reporting period is not extended, in the event that CMS determines 20 percent or more of an ACO's assigned beneficiaries for the performance year, as determined under subpart E of this part, reside in an area identified under the Quality Payment Program as being affected by an extreme and uncontrollable circumstance or an ACO's legal entity is located in such an area, the following approach is used in calculating the quality score instead of the methodology specified in paragraphs (a) through (e) of this section.

(1) The ACO's minimum quality performance score is set to equal the mean quality performance score for all Shared Savings Program ACOs for performance year 2017.

(2) If the ACO completely and accurately reports all quality measures, CMS uses the higher of the ACO's quality performance score or the mean quality performance score for all Shared Savings Program ACOs.

(3) CMS applies determinations made under the Quality Payment Program with respect to—

(i) Whether an extreme and uncontrollable circumstance has occurred; and

(ii) The affected areas.

(4) An ACO's legal entity location is based on the address on file for the ACO in CMS' ACO application and management system.

(5) CMS has sole discretion to determine the time period during which an extreme and uncontrollable circumstance occurred, the percentage of the ACO's assigned beneficiaries residing in the affected areas, and the location of the ACO legal entity.

■ 3. Amend § 425.606 by adding paragraph (i) to read as follows:

§ 425.606 Calculation of shared savings and losses under Track 2.

* * * * *

(i) *Extreme and uncontrollable circumstances.* For performance year 2017, the following adjustment is made in calculating the amount of shared losses, after the application of the shared loss rate in paragraph (f) of this section and the loss recoupment limit in paragraph (g) of this section.

(1) CMS determines the percentage of the ACO's performance year 2017 assigned beneficiary population affected by an extreme and uncontrollable circumstance.

(2) CMS reduces the amount of the ACO's shared losses by an amount determined by multiplying the shared losses by the percentage of the total months in the performance year affected by an extreme and uncontrollable circumstance, and the percentage of the ACO's assigned beneficiaries who reside in an area affected by an extreme and uncontrollable circumstance.

(3) CMS applies determinations made under the Quality Payment Program with respect to—

(i) Whether an extreme and uncontrollable circumstance has occurred; and

(ii) The affected areas.

(4) CMS has sole discretion to determine the time period during which an extreme and uncontrollable circumstance occurred and the percentage of the ACO's assigned beneficiaries residing in the affected areas.

■ 4. Amend § 425.610 by adding paragraph (i) to read as follows:

§ 425.610 Calculation of shared savings and losses under Track 3.

* * * * *

(i) *Extreme and uncontrollable circumstances.* For performance year

2017, the following adjustment is made in calculating the amount of shared losses, after the application of the shared loss rate in paragraph (f) of this section and the loss recoupment limit in paragraph (g) of this section.

(1) CMS determines the percentage of the ACO's performance year 2017 assigned beneficiary population affected by an extreme and uncontrollable circumstance.

(2) CMS reduces the amount of the ACO's shared losses by an amount determined by multiplying the shared losses by the percentage of the total months in the performance year affected by an extreme and uncontrollable circumstance, and the percentage of the ACO's assigned beneficiaries who reside in an area affected by an extreme and uncontrollable circumstance.

(3) CMS applies determinations made under the Quality Payment Program with respect to—

(i) Whether an extreme and uncontrollable circumstance has occurred; and

(ii) The affected areas.

(4) CMS has sole discretion to determine the time period during which an extreme and uncontrollable circumstance occurred and the percentage of the ACO's assigned beneficiaries residing in the affected areas.

Dated: November 28, 2017.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: November 30, 2017.

Eric D. Hargan,

Acting Secretary, Department of Health and Human Services.

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