

EPA-APPROVED IOWA REGULATIONS—Continued

Iowa citation	Title	State effective date	EPA approval date	Explanation
567–33.3	Special Construction Permit Requirements for Major Stationary Sources in Areas Designated Attainment or Unclassified (PSD).	3/22/17	6/8/2018, [Insert Federal Register citation].	Provisions of the 2010 PM _{2.5} PSD—Increments, SILs and SMCs rule (published October 20, 2010) relating to SILs and SMCs that were affected by the January 22, 2013, U.S. Court of Appeals decision are not SIP approved. Iowa’s rule incorporating EPA’s 2007 revision of the definition of “chemical processing plants” (the “Ethanol Rule,” (published May 1, 2007) or EPA’s 2008 “fugitive emissions rule,” (published December 19, 2008) are not SIP-approved.
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PART 62—APPROVAL AND PROMULGATION OF STATE PLANS FOR DESIGNATED FACILITIES AND POLLUTANTS

■ 3. The authority citation for part 62 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart Q—Iowa

■ 4. Amend § 62.3913 by revising paragraph (d) and adding paragraph (e) to read as follows:

§ 62.3913 Identification of plan.

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(d) *Amended plan, submitted September 19, 2001.* Clarifying revisions to the plan with regard to design capacity reports for control of air emissions from municipal solid waste landfills submitted by the Iowa Department of Natural Resources on September 19, 2001. The amended plan was effective February 11, 2002.

(e) *Amended plan, submitted April 13, 2017.* Grammatical revision to the plan for the control of air emissions from municipal solid waste landfills submitted by the Iowa Department of Natural Resources, on April 13, 2017. The state effective date of the revision was March 22, 2017. The effective date of the amended plan is August 7, 2018.

PART 70—STATE OPERATING PERMIT PROGRAMS

■ 5. The authority citation for part 70 continues to read as follows:

Authority: 42 U.S.C. 7401, *et seq.*

■ 6. Amend appendix A to part 70 by adding paragraph (r) under the heading “Iowa” to read as follows:

Appendix A to Part 70—Approval Status of State and Local Operating Permits Programs

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Iowa

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(r) The Iowa Department of Natural Resources submitted for program approval revisions to rules 567–22.100, 567–22.103, 567–22.105, and 567–22.108. The state effective date was March 22, 2017. This revision is effective August 7, 2018.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 510

[CMS–5524–F2]

RIN 0938–AT16

Medicare Program; Changes to the Comprehensive Care for Joint Replacement Payment Model (CJR): Extreme and Uncontrollable Circumstances Policy for the CJR Model

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

ACTION: Final rule.

SUMMARY: This final rule finalizes a policy that provides flexibility in the determination of episode spending for Comprehensive Care for Joint Replacement Payment Model (CJR) participant hospitals located in areas impacted by extreme and uncontrollable circumstances for performance years 3 through 5.

DATES: Effective July 9, 2018.

FOR FURTHER INFORMATION CONTACT: Heather Holsey, (410) 786–0028. For

questions related to the CJR model: CJR@cms.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In the Medicare Program; Cancellation of Advancing Care Coordination Through Episode Payment and Cardiac Rehabilitation Incentive Payment Models; Changes to Comprehensive Care for Joint Replacement Payment Model: Extreme and Uncontrollable Circumstances Policy for the Comprehensive Care for Joint Replacement Payment Model final rule and interim final rule with comment period published on December 1, 2017 (82 FR 57066 through 57104), we issued an interim final rule with comment period in conjunction with the final rule in order to address the need for a policy to provide some flexibility in the determination of episode costs for providers located in areas impacted by extreme and uncontrollable circumstances. Specifically, we finalized an extreme and uncontrollable events policy for the performance years 2 through 5 reconciliation and sought comment on potential refinements we might make to this policy for future performance year reconciliations after performance year 2. The 30-day comment period for that rule closed on January 30, 2018. We received 3 comments on our comment solicitation on potential refinements we might make to the extreme and uncontrollable circumstances policy for future performance year reconciliations after performance year 2. Those 3 comments and our responses are discussed in the following paragraphs. We also received 4 comments that did not relate to the extreme and uncontrollable circumstances policy comment solicitation.

II. Provisions of the Interim Final Rule With Comment Period and Analysis of and Response to Public Comments

A. Overview and Background

In the interim final rule with comment period published on December 1, 2017, we established an extreme and uncontrollable circumstances policy for CJR performance years 2 through 5 reconciliation to provide some flexibility in determining episode spending for CJR participant hospitals located in areas impacted by extreme and uncontrollable circumstances. While this policy most notably addressed Hurricane Harvey, Hurricane Irma, Hurricane Nate, and the California wildfires of August, September, and October 2017, we noted that this policy could also include other similar events that occur within a given performance year, including performance year 2, if those events meet the requirements we set forth in this policy. While Hurricane Maria, which also occurred in the same timeframe, had and, as of the writing of this final rule, continues to have a significant and crippling effect on Puerto Rico and the U.S. Virgin Islands, Hurricane Maria was not part of the interim final rule with comment period as the CJR model is not in operation in the areas impacted by Hurricane Maria, and, therefore there are no CJR participant hospitals that have been impacted by Hurricane Maria. Hurricane Harvey, Hurricane Irma, Hurricane Nate, and the California wildfires of August, September, and October of 2017 affected large regions of the United States where the CJR model operates, leading to widespread destruction of infrastructure that impacted residents' ability to continue normal functions afterwards.

As we stated in the interim final rule with comment period, at least 101 CJR participant hospitals are located in the areas affected by Hurricane Irma and Hurricane Harvey, at least 22 CJR participant hospitals are located in areas impacted by the California wildfires and approximately 12 are in the areas affected by Hurricane Nate. Based on a review of news articles focusing on the hurricanes, at least 35 hospitals evacuated for Hurricane Irma¹ and several hospitals evacuated at least partially for Hurricane Harvey.² In

Florida, at least two CJR participant hospitals in Miami, (Anne Bates Leach Eye Hospital and University of Miami Hospital) and one CJR participant hospital in Miami Beach—Mount Sinai Medical Center—had to close because of Hurricane Irma.³ Tampa General Hospital, a CJR participant hospital in Tampa, evacuated all patients except for those too ill to move.⁴ In response to Hurricane Irma, on September 9, 2017, Tampa Community Hospital, a CJR participant hospital, suspended all services and evacuated all patients to two other CJR participant hospitals, Brandon Regional Hospital and Medical Center of Trinity.⁵ In Texas, Baptist Beaumont Hospital, a CJR participant hospital in Beaumont, Texas, had to shut down and evacuate on August 31, 2017.⁶ On the same day, Christus Southeast Texas St. Elizabeth, another CJR participant hospital in Beaumont, Texas, left only the emergency and trauma center of the hospital open in order to ensure it had enough water for the patients still at the hospital.⁶ Patients seeking care at the Medical Center of Southeast Texas, a CJR participant hospital in Port Arthur, Texas, had to be taken by dump truck through the submerged hospital parking lot to the perimeter of the property, where a boat would take them to the hospital.⁶ An additional review of news related to California wildfires also shows that the fires caused various hospitals to evacuate patients.⁷ On November 16, 2017, five counties in Alabama were declared as major disaster areas due to the destruction of structures, piers, roads and bridges caused by Hurricane Nate.⁶ Although we did not yet have enough data to evaluate these event-specific effects on

³ Hurricane Irma causes 36 Florida hospitals to close. September 12, 2017. <https://www.healthdatamanagement.com/news/hurricane-irma-causes-36-florida-hospitals-to-close>. Accessed November 22, 2017.

⁴ At Tampa Hospital in Evacuation Zone, 800 Patients and Staff Ride Out Hurricane Irma. September 10, 2017. <https://weather.com/storms/hurricane/news/hurricane-irma-tampa-hospital-evacuation-zone>. Accessed November 22, 2017.

⁵ Tampa Community Hospital has suspended all services and has evacuated patients. September 9, 2017. <https://tampacommunityhospital.com/about/newsroom/tampa-community-hospital-has-suspended-all-services-and-has-evacuated-patients>. Accessed November 22, 2017.

⁶ http://www.al.com/news/mobile/index.ssf/2017/11/trump_declares_major_disaster.html.

⁷ Tia Powell, Dan Hanfling, and Lawrence O. Gostin. Emergency Preparedness and Public Health: The Lessons of Hurricane Sandy. *JAMA*. 2012;308(24):2569–2570. doi:10.1001/jama.2012.108940; and Christine S. Cocanour, Steven J. Allen, Janine Mazabob, John W. Sparks, Craig P. Fischer, Juanita Romans, Kevin P. Lally. Lessons Learned From the Evacuation of an Urban Teaching Hospital. *Arch Surg*. 2002; 137(10):1141–1145. doi:10.1001/archsurg.137.10.1141.

CJR episodes at the time of the publication of the interim final rule with comment period, we stated that we anticipated that at least some CJR participant hospitals might have experienced episode cost escalation as a result of hurricane or fire damage and subsequent emergency evacuations.

Under § 510.305(e), as of performance year 2, CJR participant hospitals who have episode costs as calculated under § 510.305(e)(1)(iii) (for example, episode costs that exceed the target price for the performance year) will owe CMS 5 percent of the loss. While the intent of this loss repayment policy is to incentivize providers to manage costs while improving the quality of CJR patient care, we noted in the interim final rule with comment period that in extreme and uncontrollable circumstances, prudent patient care management might involve potentially expensive air ambulance transport or prolonged inpatient stays when other alternatives are not practical due, for example, to state and local mandatory evacuation orders or compromised infrastructure. In addition to the news reports of disaster conditions that impacted several CJR participant hospitals, a number of research studies on natural disasters and rushed evacuations for hospitals supported our assumption that costs can rise during disaster situations.⁷

Prior to January 1, 2018, the effective date of the interim final rule with comment period, CJR regulations at § 510.210 did not allow cancellation of episodes for extreme and uncontrollable circumstances. The CJR regulations at § 510.305 also did not permit an adjustment to account for episode spending that may have escalated significantly due to events driven by extreme and uncontrollable circumstances.

B. Identifying Participant Hospitals Affected by Extreme and Uncontrollable Circumstances

As discussed in the interim final rule with comment period, for purposes of developing a policy to identify hospitals affected by extreme and uncontrollable circumstances, we consulted section 1135 of the Social Security Act (the Act). That section allows the Secretary to temporarily waive or modify certain Medicare requirements to ensure that sufficient health care items and services are available to meet the needs of individuals enrolled in Social Security Act programs in the emergency area and emergency period. It also allows the Secretary to temporarily waive or modify certain Medicare requirements to ensure that providers who provide

¹ Irma forces at least 35 hospitals to evacuate patients. Here's a rundown. September 9, 2017. <https://www.statnews.com/2017/09/09/irma-hospital-evacuations-rundown/>. Accessed November 21, 2017.

² After Harvey Hit, a Texas Hospital Decided to Evacuate. Here's How Patients Got Out. September 6, 2017. <https://www.nytimes.com/2017/09/06/us/texas-hospital-evacuation.html>. Accessed November 21, 2017.

such services in good faith can be reimbursed and exempted from sanctions (absent any determination of fraud or abuse). The Secretary has invoked this authority in response to significant natural disasters such as Hurricane Katrina in 2005 and Superstorm Sandy in 2012. Though the section 1135 waiver authority enables us to take actions that give healthcare providers and suppliers greater flexibility, it does not allow for payment adjustment for participant hospitals in the CJR model. However, as we noted in the interim final rule with comment period, the extreme and uncontrollable circumstance policy should only apply when a disaster is widespread and extreme. A section 1135 waiver identifies the “emergency area” and “emergency period,” as defined in section 1135(g) of Act, for which waivers are available. As we stated in the interim final rule with comment period, we believe it is appropriate to establish an extreme and uncontrollable circumstance policy that applies only when and where the magnitude of the event calls for the use of special waiver authority to help providers respond to the emergency and continue providing care.

In the interim final rule with comment period, we noted that the extreme and uncontrollable circumstance policy also should be tailored to the specific areas experiencing the extreme and uncontrollable circumstance. Section 1135 waivers typically are authorized for a geographic area that may encompass a greater region (that is, an entire state) than is directly and immediately affected by the relevant emergency. In addition, section 1135(g) of the Act defines the emergency area as that area covered by both a Secretarial and a Presidential declaration; consequently, the scope of the emergency area is not entirely in the Secretary’s control.⁸ For purposes of this policy, we stated that a narrower geographic scope, rather than the full emergency area, would ensure that the payment policy adjustment is focused on the specific areas that experienced the greatest adverse effects from the extreme and uncontrollable circumstance and is not applied to areas sustaining little or no adverse effects.

Therefore, to narrow the scope of this policy to ensure it is applied to those providers most likely to have experienced the greatest adverse effects, we also required that the area be declared as a major disaster area under

the Stafford Act. Once an area is declared as a major disaster area under the Stafford Act, the specific counties, municipalities, parishes, territories, and tribunals that are part of the major disaster area are identified and can be located on the Federal Emergency Management Agency (FEMA) website at www.FEMA.gov/disasters.

For this policy, only major disaster declarations under the Stafford Act in combination with issued section 1135 waivers are used to identify the specific counties, municipalities, parishes, territories, and tribunals where the extreme and uncontrollable circumstance took place. Using the major disaster declaration as a requirement for the extreme and uncontrollable event policy also ensures that the policy will apply only when the event is extreme, meriting the use of special authority, and targeting the specific area affected by the extreme and uncontrollable circumstance. As we noted in the interim final rule with comment period, we are not including emergency declarations under the Stafford Act or national emergency declarations under the National Emergencies Act in this policy, even if such a declaration serves as a basis for the Secretary’s invoking the section 1135 waiver authority. This is because we believe it is appropriate for our extreme and uncontrollable circumstance policy to apply only in the narrow circumstance where the circumstance constitutes a major disaster, which are more catastrophic in nature and tend to have significant impacts to infrastructure, rather than the broader grounds for which an emergency could be declared.

In the policy we established to define extreme and uncontrollable circumstances for the CJR model, an area is identified as having experienced ‘extreme and uncontrollable circumstances,’ if it is within an “emergency area” and “emergency period” as defined in section 1135(g) of the Act, and also is within a county, parish, U.S. territory or tribal government designated in a major disaster declaration under the Stafford Act.

As we stated in the interim final rule with comment period, we believe Hurricane Harvey, Irma, and Nate and the California wildfires in August, September, and October of 2017 triggered the automatic extreme and uncontrollable circumstance policy we adopted in the interim final rule with comment period. For the performance year 2 reconciliation conducted in March 2018, this extreme and uncontrollable circumstance policy

applies to those CJR participant hospitals whose CMS Certification Number (CCN) has a primary address located in a state, U.S. territory, or tribal government that is within an “emergency area” and “emergency period,” as those terms are defined in section 1135(g) of the Act, for which the Secretary has issued a waiver under section 1135 of the Act and that is designated in a major disaster declaration under the Stafford Act. The states and territories for which section 1135 waivers were issued in response to Hurricanes Harvey, Irma, Nate, and the California wildfires (during the fall of 2017) are Alabama, California, Florida, Georgia, South Carolina, Texas, Louisiana, and Mississippi. Section 1135 waivers also were issued for Puerto Rico and the Virgin Islands as a result of Hurricane Maria, but, as we noted in the interim final rule with comment period, there are no CJR participant hospitals with CCNs with a primary address in either of these areas. To view the 1135 waiver documents and for additional information on section 1135 waivers see: <https://www.cms.gov/About-CMS/Agency-Information/Emergency/>. The major disaster declarations are located on FEMA website at <https://www.fema.gov/disasters>. When locating the counties, municipalities, parishes, tribunals, and territories for the major disaster declaration, FEMA designates these locations as ‘designated areas’ for that specific state, or tribunal. All counties, municipalities, parishes, tribunals, and territories identified as designated areas on the disaster declaration are included.

The counties, parishes, and tribal governments that met the criteria for the CJR policy on extreme and uncontrollable circumstances in performance year 2 are as follows:⁹

- The following counties in Alabama: Autauga, Baldwin, Choctaw, Clarke, Dallas, Macon, Mobile, and Washington.¹⁰
- The following counties in California: Butte, Lake, Mendocino, Napa, Nevada, Orange, Sonoma, and Yuba.¹¹
- All 67 counties¹² and Big Cypress Indian Reservation, Brighton Indian Reservation, Fort Pierce Indian

⁹ The Secretary issued Mississippi a waiver under section 1135 for Hurricane Nate. However the President did not issue a major disaster declaration (An emergency disaster declaration was issued.), so under this policy Mississippi is not included on this list.

¹⁰ <https://www.fema.gov/disaster/4349/designated-areas>.

¹¹ <https://www.fema.gov/disaster/4344/designated-areas>.

¹² <https://www.fema.gov/disaster/4337/designated-areas>.

⁸ See section 1135(g) of the Act for the definition of “emergency area; emergency period”.

Reservation, Hollywood Indian Reservation, Immokalee Indian Reservation, and Tampa Reservation in Florida.¹³

- All 159 counties in Georgia.¹⁴
- All 46 counties, and the Catawba Indian Reservation in South Carolina.¹⁵
- The following counties in Texas:

Aransas, Austin, Bastrop, Bee, Bexar, Brazoria, Calhoun, Chambers, Colorado, Dallas, Dewitt, Fayette, Fort Bend, Galveston, Goliad, Gonzales, Hardin, Harris, Jackson, Jasper, Jefferson, Karnes, Kleberg, Lavaca, Lee, Liberty, Matagorda, Montgomery, Newton, Nueces, Orange, Polk, Refugio, Sabine, San Jacinto, San Patricio, Tarrant, Travis, Tyler, Victoria, Walker, Waller, and Wharton.¹⁶

- The following parishes in Louisiana: Acadia, Allen, Assumption, Beauregard, Calcasieu, Cameron, De Soto, Iberia, Jefferson Davis, Lafayette, Lafourche, Natchitoches, Plaquemines, Rapides, Red River, Sabine, St. Charles, St. Mary, Vermilion, and Vernon.¹⁷

Using these criteria, in the interim final rule with comment period, we stated that we were able to identify at least 101 CJR participant hospitals located in the areas affected by Hurricanes Harvey and Hurricane Irma, approximately 12 CJR participant hospitals in the areas affected by Hurricane Nate, and at least 22 CJR participant hospitals in areas impacted by the California wildfires. As there are no CJR model areas in Puerto Rico or the U.S. Virgin Islands, we again noted that no CJR participant hospitals were impacted by Hurricane Maria. CJR participant hospitals for whom this extreme and uncontrollable circumstances policy applies for performance year 2 (and subsequent performance years if and when the policy is invoked) receive notification via the initial reconciliation reports CMS delivers to providers upon completion of the reconciliation calculations, which under § 510.305(d) are initiated beginning 2 months after the close of the performance year.

Though the Hurricanes and California wildfires were the driving force for developing the extreme and uncontrollable circumstance policy, in the interim final rule with comment period, we stated that this policy is

being implemented for the duration of the CJR model, and that we are amending the CJR regulations accordingly, as further outlined later in this final rule.

C. Provisions for Adjusting Episode Spending Due to Extreme and Uncontrollable Circumstances

In the interim final rule with comment period, we noted that without a policy to provide CJR participant hospitals some flexibility in extreme and uncontrollable circumstances, we might inadvertently create an incentive to place cost considerations above patient safety, especially in the later years of the CJR model when the downside risk percentage increases. In considering policy alternatives to help ensure beneficiary protections by mitigating participant hospitals' financial liability for costs resulting from extreme and uncontrollable circumstances, we considered and rejected a blanket cancellation of all episodes occurring during the relevant period. As we stated in the interim final rule with comment period, we do not believe that a blanket cancellation would be in either beneficiaries' or CJR participant hospitals' best interests, as it is possible that hospitals can manage costs and earn a reconciliation payment despite these extreme and uncontrollable circumstances.

Furthermore, we would not want CJR participant hospitals to limit case management services for beneficiaries in CJR episodes during extreme and uncontrollable circumstances, when prudent care management could potentially involve using significantly more expensive transport or care settings. Therefore, we determined that capping the actual episode spending at the target amounts for those episodes would be the best way to protect beneficiaries from potential care stinting and hospitals from escalating costs. As we stated in the interim final rule with comment period, this will also ensure that those hospitals are still able to earn reconciliation payments on those eligible episodes where the disaster did not have a noticeable impact on cost.

In determining the start date of episodes to which this extreme and uncontrollable circumstances policy will apply, we determined that a window of 30 days prior to and including the date that the emergency period (as defined in section 1135(g) of the Act) begins should reasonably capture those beneficiaries whose high CJR episode costs could be attributed to extreme and uncontrollable circumstances. As we stated in the interim final rule with comment period,

we believe this 30-day window is particularly appropriate due to the 90-day CJR model episode length. Including all episodes that begin within 30 days before the date the emergency period begins should enable us to include the majority of beneficiaries still in institutional settings and who are still within the first third of their episodes when the extreme and uncontrollable circumstance arises. We note that the average length of stay for DRG 469 is between 5 and 6 days and the average length of stay for DRG 470 is between 2 and 3 days (see <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Downloads/FY2018-CMS-1677-FR-Table-5.zip>).

Under § 510.300(a)(1), we differentiated fracture and non-fracture CJR episodes and pricing, noting that lower extremity joint replacement procedures performed as a result of a hip fracture are typically emergent procedures. Fracture episodes typically occur for beneficiaries with more complex health issues and can involve higher episode spending. As we stated in the interim final rule with comment period, we do not expect a high volume of CJR non-fracture episodes to be initiated once extreme and uncontrollable circumstances arise, given that it is not prudent to conduct non-fracture major joint replacement surgeries, which generally are elective and non-emergent, until conditions stabilize and infrastructure is reasonably restored. Therefore, for non-fracture episodes, the extreme and uncontrollable circumstances policy we established in the interim final rule with comment period only applies to dates of admission to anchor hospitalization that occur between 30 days before and up to the date on which the emergency period (as defined in section 1135(g) of the Act) begins. We believe this policy empowers hospitals to decide whether they can safely and appropriately perform non-fracture THA and TKA procedures after the commencement of the emergency period and whether or not performing these procedures will subject their organization to undue financial risk resulting from increased costs that are beyond the organization's control.

However, for CJR fracture episodes, the extreme and uncontrollable circumstances policy we established in the interim final rule with comment period applies to dates of admission to the anchor hospitalization that occur within 30 days before, on, or up to 30 days after the date the emergency period (as defined in section 1135(g) of the Act) begins. As we stated in the interim final

¹³ <https://www.fema.gov/disaster/4341/designated-areas>.

¹⁴ <https://www.fema.gov/disaster/4338/designated-areas>.

¹⁵ <https://www.fema.gov/disaster/4346/designated-areas>.

¹⁶ <https://www.fema.gov/disaster/4332/designated-areas>.

¹⁷ <https://www.fema.gov/disaster/4345/designated-areas>.

rule with comment period, we recognize that fracture cases in CJR are often emergent and unplanned, and it may not be prudent to postpone major joint surgical procedures in many of those CJR fracture cases. Therefore, fracture episodes with a date of admission to the anchor hospitalization that is on or within 30 days before or after the date that the emergency period (as defined in section 1135(g) of the Act) begins are subject to this extreme and uncontrollable circumstances policy. As we stated in the interim final rule with comment period, we believe that this 30-day window before and after the emergency period should ensure that hospitals caring for CJR fracture patients during extreme and uncontrollable circumstances are adequately protected from episode costs beyond their control.

In the interim final rule with comment period, we established that, for performance years 2 through 5, for participant hospitals that are located in an emergency area during an emergency period, as those terms are defined in section 1135(g) of the Act, for which the Secretary has issued a waiver under section 1135 of the Act, and in a county, parish, U.S. territory or tribal government designated in a major disaster declaration under the Stafford Act, the following conditions apply. For a non-fracture episode with a date of admission to the anchor hospitalization that is on or within 30 days before the date that the emergency period (as defined in section 1135(g) of the Act) begins, actual episode payments are capped at the target price determined for that episode under § 510.300. For a fracture episode with a date of admission to the anchor hospitalization that is on or within 30 days before or after the date that the emergency period (as defined in section 1135(g) of the Act) begins, actual episode payments are capped at the target price determined for that episode under § 510.300.

We codified this new extreme and uncontrollable circumstance policy at § 510.305(k). We sought comment on potential refinements to this policy for future performance year reconciliations after performance year 2.

Comment: All of the comments we received in response to our comment solicitation expressed support for an extreme and uncontrollable circumstances policy for the CJR model. All commenters supported the application of the policy to episodes with anchor stays beginning on or within 30 days before the date of the emergency period. A commenter supported the policy as established in the interim final rule with comment period and stated that it should apply to

future performance years beyond performance year 2. Another commenter, who also supported the policy, noted that due to the substantial disruptions in the post-acute care market from significant infrastructure damage, the policy could be significantly improved if CMS capped payments for both fracture and non-fracture episodes with an anchor hospitalization within 30 days before or after the date that the emergency period begins. A different commenter, who also supported the policy, urged CMS to expand it to include more episodes by developing specific, recovery-focused criteria, such as the number of patients remaining displaced from their homes, the proportion of health care services remaining unavailable and distance to comparable services for rural areas to determine the end date for episodes. This commenter, who noted that extensive damage to infrastructure, housing and post-acute care services in Texas due to Hurricane Harvey continue to be substantial in certain counties, stated that delaying services to Medicare beneficiaries who meet the criteria for LEJR is detrimental to the health and well-being of the beneficiaries. This commenter recommended that the extreme and uncontrollable circumstances policy for all CJR episodes should apply to dates of admission to anchor hospitalization that occur 30 days before the emergency period (as defined in section 1135(g) of the Act) begins and up to 90 days after the date the emergency period ends or when health care services has reached 90 percent of the pre-emergency period level and beneficiary displacement issues have been resolved to ensure CJR participants are protected from episode costs beyond their control.

Response: We appreciate the support expressed by commenters for our extreme and uncontrollable circumstances policy and agree with commenters that it is appropriate for the policy to cover both fracture and non-fracture episodes with anchor stays occurring on or within 30 days before the date of the emergency period. In response to the commenter who stated that our extreme and uncontrollable circumstances policy should apply to future performance years, we can confirm that it does. While we note that recovery efforts from major disasters can take extensive time and resources, as we stated in the interim final rule with comment period, we continue to believe that it is not prudent to conduct non-fracture major joint replacement surgeries, which generally are elective and non-emergent, until conditions

stabilize and infrastructure is reasonably restored. Although we acknowledge that joint replacements can have a substantial impact on quality of life for beneficiaries, we are not persuaded by commenters that it is appropriate to extend the extreme and uncontrollable events policy to non-fracture CJR episodes beginning on or within the 30 days after the onset of an emergency period. If lasting infrastructure damage has severely crippled post-acute care access and limited offerings in a community, we are not convinced that elective surgeries should resume, especially for beneficiaries likely to need institutional post-acute care, until there is some assurance that that care will be available.

When we originally finalized the CJR target amounts in the November 24, 2015 final rule (80 FR 73273), we distinguished between hip fracture and non-fracture CJR episodes and pricing in response to comments. Commenters on that rule noted that lower extremity joint replacement procedures performed as a result of a hip fracture are typically emergent procedures (80 FR 73301) which can be more clinically complex in nature and more costly to treat due to their emergent nature. Therefore, as we stated in the interim final rule with comment period, given the frequent emergent nature of fractures, we acknowledge that it may not be prudent to postpone major joint surgical procedures in many of those CJR cases. Consequently, we believe it is appropriate, as was established in the interim final rule with comment period, to extend coverage under the extreme and uncontrollable circumstances policy to fracture cases occurring on or within 30 days after the date of the disaster, and we thank the commenters for their support of this policy that covers fracture cases on or within 30 days of the emergency period in the extreme and uncontrollable events policy.

In considering the commenter's suggestion that we develop on-going specific, recovery-focused criteria, such as the number of patients remaining displaced from their homes, the proportion of health care services remaining unavailable and distance to comparable services for rural areas to determine the end date for episodes we note that it would be extremely difficult to establish general criteria that would apply broadly to all emergency periods that might trigger the extreme and uncontrollable circumstances policy; this type of criteria would likely need to be specific to each individual emergency period and would therefore be more subjective and less predictable

for providers in the CJR model. We believe the time-based criteria we established for this policy are more straightforward and create clear guidelines for CJR participant hospitals that may need an advanced, predictable understanding of which episodes will be subject to the extreme and uncontrollable circumstances policy. We established this policy to limit financial liability under the CJR model for participant hospitals caring for CJR fracture patients during extreme and uncontrollable circumstances where costs can escalate beyond their control. While we acknowledge that disaster recovery efforts can be prolonged beyond 30-day periods, we believe that care management planning is even more essential when communities are recovering from major disasters. However, we do not believe that altering the post emergency window from 30 to 90 days, as suggested by a commenter, would be appropriate, as a longer post emergency window might incentivize providers to disengage from the care management the CJR model is focused on improving.

We note a technical correction to the preamble of the interim final rule with comment period. In several places we described our extreme and uncontrollable circumstances policy as applying when a major disaster declaration served as the condition precedent to an section 1135 waiver. However, this was incorrect, as in several of the events to which our policy applies, an emergency declaration under the Stafford Act was the condition precedent for the Secretary's exercise of the section 1135 waiver authority. For example, the section 1135 waiver for Hurricane Nate was based on an emergency declaration under the Stafford Act, but a major disaster declaration under the Stafford Act subsequently was made. The regulation text at 42 CFR 510.305(k), which we are finalizing without modification, accurately reflects the policy.

III. Provisions of the Final Regulations

This final rule incorporates the provisions of the interim final rule with comment period without changes. Therefore, this extreme and uncontrollable circumstances policy, as codified at 42 CFR 510.305(k) will apply to CJR participant hospitals that are both located in an emergency area during an emergency period (as those terms are defined in section 1135(g) of the Act) for which the Secretary has issued a waiver under section 1135; and that are also located in a county, parish, or tribal government designated in a major

disaster declaration under the Stafford Act.

IV. Collection of Information Requirements

As stated in section 1115A(d)(3) of the Act, Chapter 35 of title 44, United States Code, shall not apply to the testing and evaluation of models under section 1115A of the Act. As a result, the information collection requirements contained in this final rule need not be reviewed by the Office of Management and Budget. However, we have summarized the anticipated cost burden associated with the information collection requirements in section V. (Regulatory Impact Statement) of this final rule.

V. Regulatory Impact Statement

We have examined the impact of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. 804(2)), and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A Regulatory Impact Analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year). This rule does not reach the economic threshold and thus is not considered a major rule.

The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of less than \$7.5 million to \$38.5 million in any 1 year. Individuals and states are not included in the definition of a small entity. We are not preparing an analysis for the RFA because we have determined, and the Secretary certifies,

that this final rule will not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare an RIA if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because we have determined, and the Secretary certifies, that this final rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. In 2018, that threshold is approximately \$150 million. This rule will have no consequential effect on state, local, or tribal governments or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications. Since this regulation does not impose any costs on state or local governments, the requirements of Executive Order 13132 are not applicable.

Executive Order 13771, titled Reducing Regulation and Controlling Regulatory Costs, was issued on January 30, 2017. It has been determined that this final rule is not a "significant regulatory action" and thus does not trigger the aforementioned requirements of Executive Order 13771.

In the December 1, 2017 interim final rule with comment period, we utilized 2016 CJR episode level data to approximate the impact to projected CJR model savings resulting from the extreme and uncontrollable circumstances policy for performance year 2 (82 FR 57096). Specifically, we first identified the CJR participant hospitals located in Alabama, California, Florida, Georgia, South Carolina, Mississippi, Texas, and Louisiana (those states for which 1135 waivers were issued) that were also located in the counties listed in section

II.B. of this final rule and listed on www.FEMA.gov/disasters as having a major disaster declaration. To approximate the date of the emergency, we used the date of the disasters as listed on the FEMA website from 2017 (resetting the year to 2016 to align with the claim dates of service) and selected all CJR episodes for these providers that initiated in the month preceding (that is, 30 days prior) the date of the disaster. Date of disaster declaration dates were matched to the CJR participant hospitals based on the hospitals' state addresses.

For non-fracture episodes, we capped the actual episode payment at the target price determined for that episode if the date of admission to the anchor hospitalization was on or within 30 days before the date that the emergency period (as defined in section 1135(g) of the Act) begins. For fracture episodes, we capped the actual episode payment at the target price determined for that episode if the date of admission to the anchor hospitalization was on or within 30 days before or after the date that the emergency period (as defined in section 1135(g) of the Act) begins. Our analyses indicated that the impact of capping the actual episode payments at the episode target prices based on the 2017 extreme and uncontrollable circumstances policy could result in a decrease to the CJR model estimated savings ranging between \$1.5 to \$5.0 million for performance year 2, quantifying the dollar impact for that year based on a point estimate of \$2 million. We also noted that this performance year 2 projected impact was mitigated by the 5 percent stop-loss/stop-gain levels applicable to performance year 2 and added that if these disasters had occurred in a future performance year with higher stop-loss/stop-gain levels

then we would expect the projected impact to increase. The performance year 2 savings estimates did not assume any change in spending or volume due to these extreme and uncontrollable circumstances, neither before nor after the date of the disaster as listed on the FEMA website.

For purposes of assessing the impact of finalizing this policy for performance years 3 through 5, we note that we are unable to accurately or reasonably model an impact due to our inability to predict future disaster events. It is entirely possible future years could be completely free of major disasters and emergencies that might qualify as triggering events under the extreme and uncontrollable circumstances policy. Likewise, it is entirely possible that future years could have many more significant disaster events that might qualify as triggering events for the extreme and uncontrollable circumstances policy. In the absence of any future knowledge of potential disasters that might qualify as events that would invoke the extreme and uncontrollable circumstances policy, we are assuming that the performance year 2 extreme and uncontrollable circumstances \$1.5 to \$5 million range estimate, quantified using a 2 million dollar point estimate, can be extrapolated across the remaining 3 performance years of the CJR model since we modeled this using knowledge of actual 2017 events. Extrapolating the \$2 million per year across performance years 3 through 5 results in an estimated cost of \$6 million which could potentially net against savings predicted for the CJR model. We note that extrapolating the range estimate could make the impact of this policy for the remaining 3 years of the model as low

as \$4.5 million or as high as \$15 million. However, we again reiterate that this assumption may be inaccurate as this \$2 million per year figure was based on an estimate of known events in 2017 on modeled payments for performance year 2. Specifically, future years could be disaster free or could experience more frequent and destructive disasters, either of which could render this impact estimate incorrect. However, in absence of future knowledge we believe this extrapolation estimate can be used to approximate an impact for this extreme and uncontrollable circumstances policy for performance years 3 through 5 of the CJR model.

In accordance with the provisions of Executive Order 12866, this final rule was reviewed by the Office of Management and Budget.

List of Subjects in 42 CFR Part 510

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

For the reasons set forth in the preamble, the interim final rule published in the December 1, 2017 **Federal Register** (82 FR 57066), is adopted as final without change.

Dated: May 14, 2018.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: May 16, 2018.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

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