



## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Centers for Medicare & Medicaid Services**

**42 CFR Parts 402, 403, 411, 412, 422, 423, 460, 483, 488, and 493**

**[CMS-6076-RCN3]**

**RIN 0991-AC07**

### **Medicare and Medicaid Programs; Adjustment of Civil Monetary Penalties for Inflation; Continuation of Effectiveness and Extension of Timeline for Publication of the Final Rule**

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

**ACTION:** Continuation of effectiveness and extension of timeline for publication of the final rule.

**SUMMARY:** This document announces the continuation of, effectiveness of, and the extension of the timeline for publication of a final rule. We are issuing this document in accordance with the Social Security Act (the Act), which allows an interim final rule to remain in effect after the expiration of the timeline specified in the Act if the Secretary publishes a notice of continuation explaining why we did not comply with the regular publication timeline.

**DATES:** Effective September 3, 2021, the Medicare provisions adopted in the interim final rule published on September 6, 2016 (81 FR 61538) continue in effect and the regular timeline for publication of the final rule is extended for an additional year, until September 6, 2022.

**FOR FURTHER INFORMATION CONTACT:** Steve Forry (410) 786-1564 or Jaqueline Cipa (410) 786-3259.

**SUPPLEMENTARY INFORMATION:** Section 1871(a) of the Social Security Act (the Act) sets forth certain procedures for promulgating regulations necessary to carry out

the administration of the insurance programs under Title XVIII of the Act. Section 1871(a)(3)(A) of the Act requires the Secretary, in consultation with the Director of the Office of Management and Budget (OMB), to establish a regular timeline for the publication of final regulations based on the previous publication of a proposed rule or an interim final rule. In accordance with section 1871(a)(3)(B) of the Act, such timeline may vary among different rules, based on the complexity of the rule, the number and scope of the comments received, and other relevant factors. However, the timeline for publishing the final rule, cannot exceed 3 years from the date of publication of the proposed or interim final rule, unless there are exceptional circumstances. After consultation with the Director of OMB, the Secretary published a notice, which appeared in the December 30, 2004 **Federal Register** on (69 FR 78442), establishing a general 3-year timeline for publishing Medicare final rules after the publication of a proposed or interim final rule.

Section 1871(a)(3)(C) of the Act states that upon expiration of the regular timeline for the publication of a final regulation after opportunity for public comment, a Medicare interim final rule shall not continue in effect unless the Secretary publishes a notice of continuation of the regulation that includes an explanation of why the regular timeline was not met. Upon publication of such notice, the regular timeline for publication of the final regulation is treated as having been extended for 1 additional year.

On September 6, 2016 **Federal Register** (81 FR 61538), the Department of Health and Human Services (HHS) issued a department-wide interim final rule titled “Adjustment of Civil Monetary Penalties for Inflation” that established new regulations at 45 CFR part 102 to adjust for inflation the maximum civil monetary penalty amounts for the various civil monetary penalty authorities for all agencies within the Department. HHS took this action to comply with the Federal Civil Penalties Inflation Adjustment Act

of 1990 (the Inflation Adjustment Act) (28 U.S.C. 2461 note 2(a)), as amended by the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (section 701 of the Bipartisan Budget Act of 2015, (Pub. L. 114–74), enacted on November 2, 2015). In addition, this September 2016 interim final rule included updates to certain agency-specific regulations to reflect the new provisions governing the adjustment of civil monetary penalties for inflation in 45 CFR part 102.

One of the purposes of the Inflation Adjustment Act (see section 2(b)(1)) was to create a mechanism to allow for regular inflationary adjustments to federal civil monetary penalties. The 2015 amendments removed an inflation update exclusion that previously applied to the Social Security Act as well as to the Occupational Safety and Health Act. The 2015 amendments also “reset” the inflation calculations by excluding prior inflationary adjustments under the Inflation Adjustment Act and requiring agencies to identify, for each penalty, the year and corresponding amount(s) for which the maximum penalty level or range of minimum and maximum penalties was established (that is, originally enacted by Congress) or last adjusted other than pursuant to the Inflation Adjustment Act. In accordance with section 4 of the Inflation Adjustment Act, agencies were required to: (1) adjust the level of civil monetary penalties with an initial “catch-up” adjustment through an interim final rulemaking (IFR) to take effect by August 1, 2016; and (2) make subsequent annual adjustments for inflation.

In the September 2016 interim final rule, HHS adopted new regulations at 45 CFR part 102 to govern adjustment of civil monetary penalties for inflation. The regulation at 45 CFR 102.1 provides that part 102 applies to each statutory provision under the laws administered by HHS concerning civil monetary penalties, and that the regulations in part 102 supersede existing HHS regulations setting forth civil monetary penalty amounts. The civil money penalties and the adjusted penalty amounts administered by all HHS agencies are listed in tabular form in 45 CFR 102.3. In addition

to codifying the adjusted penalty amounts identified in §102.3, the HHS-wide interim final rule included several technical conforming updates to certain agency-specific regulations, including various CMS regulations, to identify their updated information, and incorporate a cross-reference to the location of HHS-wide regulations.

Because the conforming changes to the Medicare provisions were part of a larger, omnibus departmental interim final rule, we inadvertently missed setting a target date for publication of the final rule to make permanent the conforming changes to the Medicare regulations in accordance with section 1871(a)(3)(A) of the Act and the procedures outlined in the December 2004 notice. Therefore, in the January 2, 2020 **Federal Register** (85 FR 7), we published a document continuing the effectiveness of the interim final rule for an additional year, until September 6, 2020.

On January 31, 2020, pursuant to section 319 of the Public Health Service Act (PHSA), the Secretary determined that a Public Health Emergency (PHE) exists for the United States to aid the nation's healthcare community in responding to COVID-19. On March 11, 2020, the World Health Organization (WHO) publicly declared COVID-19 a pandemic. On March 13, 2020, the President declared the COVID-19 pandemic a national emergency. This declaration, along with the Secretary's January 31, 2020 declaration of a PHE, conferred on the Secretary certain waiver authorities under section 1135 of the Act. On March 13, 2020, the Secretary authorized waivers under section 1135 of the Act, effective March 1, 2020.<sup>1</sup> Effective July 20, 2021, the Secretary renewed the January 31, 2020 determination that was previously renewed on April 21, 2020, July 23, 2020, October 2, 2020, January 7, 2021, April 15, 2021, and July 19, 2021, that a PHE exists and has existed since January 27, 2020. The unprecedented nature of this national emergency has placed enormous responsibilities upon CMS to respond

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<sup>1</sup> <https://www.phe.gov/emergency/news/healthactions/section1135/Pages/covid19-13March20.aspx>.

appropriately, and resources have had to be re-allocated throughout the agency in order to be responsive.

Due to the PHE and in accordance with section 1871(a)(3)(C) of the Act, on September 8, 2020 (85 FR 55385), we published a second document continuing the effectiveness of effect and the regular timeline for publication of the final rule for an additional year, until September 6, 2021.

Because of CMS's continued efforts to address resource challenges resulting from the PHE and consistent with section 1871(a)(3)(C) of the Act, we are publishing a third notice of continuation extending the effectiveness of the technical conforming changes to the Medicare regulations that were implemented through interim final rule and to allow time to publish a final rule. Therefore, the Medicare provisions adopted in interim final regulation continue in effect and the regular timeline for publication of the final rule is extended for an additional year, until September 6, 2022.

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**Karuna Seshasai,**  
Executive Secretary to the Department,  
Department of Health and Human Services.

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