

CMS EXTENDS PUBLICATION TIMELINE OF FINAL RULE FOR WAIVERS IN CONNECTION WITH THE MEDICARE SHARED SAVINGS PROGRAM

EXECUTIVE SUMMARY

On October 17, 2014, the Centers for Medicare & Medicaid Services ("CMS") announced¹ the extension of the November 2, 2011 interim final rule with comment that established waivers of some federal fraud and abuse laws as applied to Accountable Care Organizations ("ACOs") participating in the Medicare Shared Savings Program (the "Program"). Without this extension, the interim final rule ("Waiver IFC") would have expired in November, leaving ACOs uncertain of their fraud and abuse exposure. As a result of the extension, CMS now has until November 2, 2015 to publish a final rule.

BACKGROUND

The Affordable Care Act ("ACA") authorizes the waiver of the Stark Law, the federal Anti-Kickback Statute and certain Civil Monetary Penalty provisions in order to facilitate the development and implementation of ACOs to participate in the Program. Pursuant to this authority, CMS and the Office of the Inspector General ("OIG") jointly published Waiver IFC on November 2, 2011. Waiver IFC provides five fraud and abuse waivers to remove some potential liabilities for ACOs participating in the Program. Because Waiver IFC is a Medicare rule, the timeline for publishing a final rule is not to exceed three years from the date of publication of Waiver IFC. This timeline may be extended by the Secretary publishing a notice of continuation explaining why the three year timeline was not met. CMS explained that based on stakeholder feedback and CMS's experience operating the Medicare Shared Savings Program thus far, modifications to the Program regulations were necessary. Furthermore, in the absence of an extension of the Waiver IFC, there would be significant uncertainty for ACOs participating in the Program, which would have the potential to disrupt ongoing business plans and operations. In light of the forthcoming proposed rule, CMS felt it was critical to extend Waiver IFC to allow for the continuation of the federal fraud and abuse waivers. This extension will allow ACOs to continue providing coordinated care to government health care beneficiaries until the final rule is published next year on November 2, 2015.

REQUEST FOR COMMENT

In addition to extending Waiver IFC, CMS also requested comment from industry stakeholders on the following topics:

1. How and to what extent ACOs are using the waivers;
2. Whether the existing waivers serve the needs of ACOs and the Medicare program;
3. Whether the waivers adequately protect the Medicare program and beneficiaries from the types of harms associated with referral payments or payments to reduce or limit services; and
4. Whether there are new or changed considerations that should inform the development of additional notice and comment rulemaking.

PRACTICAL TAKEAWAYS

ACOs currently participating in the Program may continue to do so under the extension of Waiver IFC without exposing themselves to risk of fraud and abuse until November 2, 2015. Any industry stakeholders who wish to provide CMS with comment on the current waivers and their effectiveness are encouraged to do so. If you have any questions or would like additional information about this topic, please contact:

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- Janice K. Pascuzzi at (317) 429-3648 or orpascuzzi@hallrender.com; or
- Your regular Hall Render attorney.

Special thanks to Maryn Wilcoxson, law clerk, for her assistance with the preparation of this Health Law News article. Please visit the Hall Render Blog at hallrender.com/resources/blog for more information on topics related to health care law.¹ For a copy of the CMS interim final rule issued on October 17, 2014, click [here](#).