American Hospital Association

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Submitted electronically

January 3, 2012

Marilyn Tavenner
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health & Human Services
Room 445-G, Hubert Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Daniel R. Levinson
Inspector General
Office of Inspector General
Department of Health & Human Services
Room 5441, Cohen Building
330 Independence Avenue, SW
Washington, DC 20201

RE: CMS – 1439 – IFC; Final Waivers in Connection with the Shared Savings Program

Dear Ms. Tavenner and Mr. Levinson:

On behalf of our more than 5,000 member hospitals, health systems and other health care organizations and our 42,000 individual members, the American Hospital Association (AHA) appreciates the opportunity to comment on the Interim Final Rule with comment period (IFC) establishing waivers from certain fraud and abuse laws for Accountable Care Organizations (ACOs) under the Medicare Shared Savings Program (ACO Program).

The AHA appreciates the significant improvements the Centers for Medicare & Medicaid Services (CMS) and the Office of Inspector General (collectively "the Agencies") made to the number of waivers for ACOs and their scope and application. We applaud the Agencies for their important effort to remove the legal and regulatory barriers to care coordination and improved quality for beneficiaries served by ACOs. The AHA urges the Agencies to extend the waivers beyond ACOs to enable the development of other clinically integrated organizations. For example, the approach reflected in these waivers would provide an excellent foundation for waivers under the Center for Medicare & Medicaid Innovation, the Medicaid program, and for removing legal and regulatory barriers more broadly. All patients who are covered under federal health programs should have the same opportunity to benefit from the quality and care coordination improvements that clinically integrated organizations can provide.

The AHA is concerned, however, that the Agencies' discussion in the IFC regarding future narrowing of the waivers undermines the "certainty" and "latitude for beneficial innovation" that

the Agencies said they intended to provide. While the waivers became effective immediately when the IFC was issued, the Agencies simultaneously requested comments on a series of questions that essentially asked whether the newly created waivers should be narrowed and whether there was a need for more definition or specificity in the waivers. The AHA's reply to both is "no."

The Agencies also requested comment on what appears to be an attempt to position CMS and the OIG to move unilaterally to narrow the current waivers significantly without providing for notice-and-comment rulemaking on the specific form of newly narrowed waivers. Even if the language of the IFC is intended only to reserve to the Agencies an opportunity to proceed in that manner – to announce narrowed waivers without further notice-and-comment – we strongly object to both the reservation and the process it contemplates. Any material change in the waivers should be made only through formal, complete and specific notice-and-comment and should apply only to ACO agreements for which the pre-participation and participation phase arise *after* any changes are finalized.

THE NEW WAIVERS SHOULD BE FINALIZED AS-IS

The Agencies struck the right balance in creating the new waivers for ACOs. They provide protections for the program and beneficiaries that are adapted to the new reality of the ACO Program. The waivers are built on and complement the parallel obligations ACOs assume under the ACO Program and the oversight that will be exercised by CMS.

First and foremost, eligibility for the pre-participation and participation waivers is dependent on the ACO arrangement being linked to advancing the goals of the ACO Program. The structure of the ACO program protects against and limits overutilization and covert payments intended to influence improperly the medical decision making of health care professionals. In addition, the specific waivers place the accountability for ensuring that arrangements further those program goals on the governing body of the ACO. The waivers and program rules mandate transparency in decision-making, requiring documentation and public disclosure requirements. Beyond those, the waivers recognize the context in which ACOs will operate, including the extensive oversight that CMS will exercise under the ACO rule. Collectively, the waivers and the ACO program rules and contract terms will serve the purposes and provide the protections afforded by the fraud and abuse laws by other, more immediately effective means.

The contractual agreement between CMS and the ACO is the primary source for ongoing oversight. Pursuant to the contract, an ACO must make significant financial and quality information publicly available and provide extensive and detailed reporting to CMS on the quality, cost and overall care of the Medicare fee-for-service beneficiaries. Standard program integrity provisions will apply to the ACOs (*e.g.*, certifications of compliance with program requirements, certifications of the accuracy, truthfulness and completeness of information submitted, and establishment of compliance programs). There are no gaps in protection that need to be filled.

While the Agencies have flagged a number of words or phrases for possible clarification (*e.g.*, "reasonably related," "preventive services," "start-up," "board determinations") all are either sufficiently familiar in current practice or adequately discussed in the context of the rule that nothing further is needed. Similarly, the Agencies have flagged potential limitations that could be added to the new waivers (*e.g.*, placing more restrictions on use of the pre-participation waiver or eliminating its availability prematurely; making waivers applicable only to ACO beneficiaries; loss of waiver for any element of noncompliance with corrective action plan). The Agencies have not, however, identified a gap or potential harm that is not already addressed in the new waivers. The newly created waivers were made effective on the date they were issued as an inducement for providers to participate in the ACO Program. To create doubt about their viability is to undermine the reliance the Agencies invite hospitals and others to place on the IFC.

CLARIFY THE FINALITY OF EXISTING WAIVERS AND ASSURE ANY CHANGE WILL BE MADE THROUGH FUTURE FORMAL RULEMAKING

The Agencies should promptly clarify the finality of the existing waivers and assure providers that any material change in the waivers will be made prospectively and through formal notice-and-comment.

As noted above, the uncertainty created by language in the IFC that implies that waivers could be narrowed significantly and abruptly without formal notice-and-comment rulemaking is very troubling. In Part V of the IFC, the Agencies acknowledge the importance of certainty and flexibility to allow for innovation in care delivery: "We are aiming for an approach that will provide ACOs with flexibility, certainty, and latitude for beneficial innovation and variation in connection with the new Shared Savings Program, while also protecting Medicare beneficiaries and the Medicare program from fraud and abuse." That approach is clearly undermined by the statements that begin 17 pages into a 20-page rule where, contrary to these goals, the Agencies announce that after closely monitoring ACOs during the first two years of the ACO Program, they plan:

> "to narrow the waivers established in this IFC *unless* the Secretary determines that information gathered through monitoring or other means suggests that such waivers have not had the unintended effect of shielding abusive relationships" (emphasis added).

Literally read, this language appears to say that unless the Secretary proves a negative – that no unintended consequences occurred – the waivers automatically will cease to exist as-is and will be narrowed. We hope this was not intended. If that is the case, we strongly disagree as a matter of law, and as a matter of good public policy.

The IFC does not provide sufficient notice to support the Agencies' establishment of new, narrower waivers in the final rule. There is no articulation of the rationale for narrowing the waivers. Indeed, there cannot be because the data the Agencies would rely on to support their changes, and that providers should have an opportunity to comment on, does not exist yet.

The AHA fully expects that CMS will appropriately exercise its oversight responsibility specific to the ACO Program and its participants (as well as its general oversight responsibilities for Medicare providers and suppliers). As the Agencies recognized in the IFC, CMS has a variety of tools to monitor the activities of the ACO and may take corrective action against an ACO that is not meeting the performance standards, including termination from the ACO Program.

We urge the Agencies to promptly issue a statement confirming that any material changes in the waivers would be subject to future notice-and-comment rulemaking. ACOs should not be at risk for changes to the rules through obscure or little noticed issuances. The Agencies also should confirm that any material changes made through future rulemaking would apply only to ACOs preparing to enter the program after those changes are promulgated. While there is language in the IFC stating that changes would not apply to existing arrangements part way through the three-year agreement, the Agencies should go further. Just as narrowing the waiver conditions mid-way in an agreement would disrupt the incentives to develop the infrastructure necessary to finding new ways to deliver care (which the Agencies acknowledge), so too, changing the rules applicable to ACOs that seek to renew their contracts after successfully meeting CMS performance and improvement standards (and developing an ACO structure that advances the goals of Congress and meets the performance standards) could undermine the progressive development of new delivery models that the program was designed to foster.

To remove any confusion caused by the IFC discussion on narrowing the waivers, the Agencies should issue these clarifying statements. If, after monitoring, the Agencies believe the waiver policies need to be revisited or changed, they should complete a new notice-and-comment process. Changing the waivers should be as deliberative a process as was the one used to create them.

We look forward to working with CMS and the OIG to continue removing the legal and regulatory barriers to providing clinically integrated care so all beneficiaries of the federal health care programs have the benefits of improved quality and care coordination. If you have any questions about our comments, please contact Maureen Mudron, deputy general counsel, at (202) 626-2301 or mmudron@aha.org.

Sincerely,

_____/S/_____
Rick Pollack
Executive Vice President