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June 6, 2011

BY ELECTRONIC SUBMISSION: [HTTP://WWW.REGULATIONS.GOV](http://www.regulations.gov)

Donald Berwick, MD

Administrator

Centers for Medicare & Medicaid Services

Department of Health and Human Services

Attention: CMS-1345-NC2

P.O. Box 8013

Baltimore, MD 21244-8013.

Re: Comments on Joint Notice [Docket No. CMS-1345-NC2]: Waiver Designs in Connection with the Medicare Shared Savings Program and the Innovation Center

Dear Dr. Berwick:

The Infectious Diseases Society of America (IDSAs) appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) and the Office of Inspector General (OIG) Joint Notice that proposes waiving anti-trust laws in certain financial situations involving Accountable Care Organizations (ACOs).

IDSAs represents more than 9,300 physicians and scientists devoted to patient care, education, research, and community health planning in infectious diseases (ID). The Society's members focus on the epidemiology, diagnosis, investigation, prevention and treatment of infectious diseases in the United States and abroad. Our members care for patients of all ages with serious infections, including meningitis, pneumonia, tuberculosis, surgical infections, those with cancer or transplants who have life-threatening infections caused by unusual or drug-resistant microorganisms, and new and emerging infections, such as severe acute respiratory syndrome (SARS) and H1N1 influenza.

The Patient Protection and Affordable Care Act (ACA) explicitly authorizes CMS to waive federal anti-trust laws, including the Civil Monetary Penalty (CMP) statute, the federal anti-kickback statute (AKS), and the Ethics in Patient Referrals (Stark) law, in order to encourage the establishment of ACOs under Medicare's Shared Savings Program. IDSAs's support for appropriate adjustments to the anti-trust laws, as a means to encourage innovations in healthcare delivery and payments, has been documented in numerous policy letters submitted prior to, during, and after the healthcare reform debate. In response to a 2009 Physician Fee Schedule (PFS) Rule proposal that would have established a shared savings (or incentive payment) exception to the Stark law, IDSAs offered its most detailed support to date for the establishment of such arrangements.

In issuing the Joint Notice, CMS and OIG take a significant and positive step in the direction of reducing existing barriers that restrict shared savings or incentive-based payments between healthcare providers. However, the Joint Notice is by definition limited in scope in that it only covers "activities necessary for" and "directly related to" the ACO's participation in and operations under the Medicare Shared Savings Program. According to CMS' estimates, only 75-150 ACOs will participate in the Shared Savings Program during the first year and, if the tone of the comments is any indication, the actual number could be even lower. This means that the vast majority of healthcare will continue to be provided in office-based practices, hospitals, long-term care facilities, and skilled nursing facilities that are not affiliated with ACOs. As such, **IDSA supports the establishment of waivers, safe harbors, and/or exceptions to federal anti-trust laws as a means to incentivize a full range of innovations in healthcare delivery and payments not only within ACOs but also throughout the entire healthcare system. These include systems-level innovations that are focused on avoiding healthcare-related complications and their associated costs, such as the costs of providing necessary care for preventable conditions.**

Moreover, even within the context of ACOs, federal anti-trust laws still pose significant barriers that the waivers proposed in the Joint Notice do not sufficiently address. Accordingly, **IDSA strongly urges CMS and OIG to issue an Interim Final Rule, rather than a Final Rule, so that appropriate adjustments can be made as provider groups gain operational experience with the ACO model.** The remainder of IDSA's comments will address specific aspects of the Joint Notice and provide alternative options for CMS to consider in future rulemaking.

WAIVERS SHOULD COVER ACTIVITIES NECESSARY TO FORM ACOs

The Joint Notice proposes waiving federal anti-trust laws for activities that are necessary for and directly related to the ACO's participation in and operations under the Medicare Shared Savings Program. These waivers would cover ACOs' distribution of shared savings during the year in which the shared savings were earned.

However, ACOs will require large infusions of capital to pay for significant start-up costs not covered by the proposed waivers and which are likely to far exceed Medicare's \$1.75 million estimate. These costs include establishing an ACO as a legal entity, conducting market and business analyses, meeting the various structural requirements, negotiating proportions of shared savings with individual ACO participants, completing the Shared Savings Program application process, and ensuring compliance with the applicable federal and state anti-trust laws. Additionally, new and innovative practice arrangements likely will be required to ensure that ACOs have the right mix of specialists, consultants, employed staff, and other providers/suppliers of care. Because it is highly unlikely that smaller ACOs or physicians within an ACO will be able to come up with the necessary capital, waivers must provide the flexibility to look to independent practice associations or other financing sources to defray these costs.

IDSA urges CMS and OIG to expand the waivers to include all necessary costs associated with establishing an ACO under the Medicare Shared Savings Program. Unless waivers are extended to these kinds of exploratory ACO activities, many financial relationships may increase anti-trust exposure, thereby impeding the development of necessary innovations.

WAIVERS SHOULD EXTEND BEYOND THE INITIAL PARTICIPATION PERIOD

The Joint Notice proposes that the waivers would apply to the distributions of shared savings payments earned by the ACO during the initial three-year participation agreement. This would apply even if the distribution of shared savings payments occurred after the end of the agreement period.

Limiting waivers to only the three-year participation period likely would preclude many (if not most) ACOs from realizing shared savings payments. To underscore this point, only five of the 10 Physician Group Practice (PGP) Demonstration¹ participants earned shared savings payments after four years. It is highly unlikely that ACOs with less operational experience will be able to realize shared savings payments in three years when half of the PGP Demonstration participants, which account for some of the most integrated delivery models in the country, failed to do so after even more time had elapsed. Accordingly, **CMS and OIG should extend waiver protection significantly beyond the three-year agreement period.**

WAIVERS SHOULD COVER ACTIVITIES BEYOND DIRECT SHARED SAVINGS

The Joint Notice proposes that waivers would cover ACOs' distribution of shared savings payments to ACO participants or ACO providers/suppliers. It is unclear whether certain types of services or contractual arrangement would be covered by these waivers.

Many ACOs will be forced to enter into contractual arrangements with providers to address specific quality or cost issues. Such arrangements may be necessary because the issues to be addressed fall outside the scope of shared savings or because the ACO does not have sufficient in-house expertise. For example, in addition to providing bedside care to patients with serious infections, ID physicians often serve as hospitals' medical directors charged with designing, implementing, and overseeing infection prevention and antimicrobial stewardship programs. These systems-level activities, which are typically reimbursed according to a calculated *fair market value*, are focused on preventing healthcare-acquired complications and their associated costs before they happen. Historically, incentive-based reimbursements for these activities have been avoided by practitioners and systems for fear of violating the Stark and CMP laws.

IDSA requests that CMS and OIG expand the Shared Savings waivers to include systems-level activities that are negotiated on a contractual basis. These activities include infection prevention and antimicrobial stewardship procedures, which are focused on preventing the need for and cost of additional patient care by avoiding the precipitating complications.

ADDITIONAL WAIVERS NEEDED TO IMPROVE HEALTHCARE DELIVERY

IDSA is generally supportive of the proposed Shared Savings waivers as long as CMS and OIG address the preceding concerns in future rulemaking. However, as was mentioned previously, IDSA strongly supports the establishment of waivers, safe harbors, and/or exceptions to federal anti-trust laws as a means to incentivize a full range of innovations throughout the entire

¹PGP Demonstration Evaluation Report: http://www.cms.gov/DemoProjectsEvalRpts/downloads/PGP_RTC_Sept.pdf

healthcare system. It is critical that such waivers incentivize not only high quality patient care but also systems-level activities that are proven to reduce unnecessary and avoidable costs.

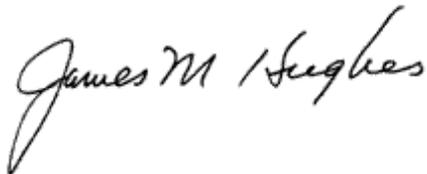
As such, **IDSA urges the newly established Center for Medicare and Medicaid Innovation (CMMI) to develop, test, and implement additional waivers nationally that will foster healthcare delivery system and payment reform.** For its part, IDSA plans to work with CMMI and OIG in the coming months to ensure that ID physicians, who serve as infection prevention and antimicrobial stewardship medical directors at their local institutions, are empowered to negotiate incentive-based payments (or gainsharing arrangements) that reward results achieved and sustained rather than time logged.

CONCLUSION

IDSA appreciates consideration of our comments in response to the proposed waivers described in the CMS and OIG Joint Notice. For additional information regarding IDSA's positions on shared savings or incentive-based payments, the 2009 PFS comment letter mentioned earlier can be downloaded at: <http://www.idsociety.org/WorkArea/showcontent.aspx?id=13434>.

If you have any questions or concerns, please feel free to contact Jason A. Scull, IDSA's Senior Program Officer of Practice and Payment Policy, at (703) 299-5146 or jscull@idsociety.org.

Sincerely,

A handwritten signature in black ink that reads "James M. Hughes". The signature is written in a cursive style with a large, looped initial "J".

James Hughes, MD, FIDSA
President, IDSA

cc:

Richard Gilfillan, MD
Acting Director, CMMI

Jonathan Blum
Director, CMM