February 26, 2013

Daniel R. Levinson, Inspector General
Office of Inspector General
Department of Health and Human Services
330 Independence Avenue SW
Washington, DC 20201

Attn: Ms. Patrice Drew

Re: File Code OIG–121–N

Dear Inspector General Levinson:

Medical Group Management Association (MGMA) appreciates the opportunity to submit these comments in response to the Department of Health and Human Services’ Office of Inspector General’s (OIG’s) annual solicitation for suggestions to improve the Federal anti-kickback statute’s “safe harbor” regulations. MGMA believes physician group practices will continue to benefit from the electronic health records (EHR) safe harbor and urges the OIG to eliminate the current “sunset” provision. This safe harbor is found at 42 C.F.R. § 1001.952 (y), and paragraph (y)(13) requires that all aspects of a qualifying EHR arrangement be completed by Dec. 31. As a result, no new EHR support arrangements from which our member practices might benefit will be eligible for safe harbor status, and others begun prior to the sunset date but not fully implemented will be at increased regulatory risk.

MGMA is the premier association for professional administrators and leaders of medical group practices. Since 1926, the Association has delivered networking, professional education and resources, advocacy and certification for medical practice professionals. The Association represents 22,500 members who lead 13,600 organizations nationwide in which some 280,000 physicians provide more than 40 percent of the healthcare services delivered in the United States.

MGMA has long been a strong proponent of EHRs and other health information technology (HIT) that produces administrative efficiencies in medical group practices while at the same time assisting physicians in the delivery of high-quality, patient-centered clinical care. Many of our member organizations have been pioneers in the development and implementation of HIT systems, and medical group practices—particularly larger ones—have typically been “early adopters” of these practice enhancements. In addition, many of our members are “meaningful users” of certified EHR technology and thus receive incentive payments under the program established by the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH). But this program alone will not be sufficient to achieve the administration’s goal of having the nation’s clinicians all using interoperable HIT. A significant number of smaller practices are unable to participate in the federal government’s EHR incentive program because of challenges related to their practice
location, specific clinical setting and Internet and other technical capabilities. In particular, we remain very concerned that the EHR incentive program’s emphasis, as well as the logistical support provided through the Regional Extension Program has been on those eligible professionals providing primary care services. Specialty physicians in smaller clinical settings continue to struggle to adopt this important technology.

There are also a number of additional factors impacting physicians’ ability to acquire and use EHRs, including:

- The high upfront cost of implementation, currently estimated by MGMA to be in excess of $40,000 per FTE physician
- The continuing costs of operating and maintaining such systems, estimated to be in excess of $15,000 per FTE physician per year
- The fluid nature of the technology involved, with multiple vendors offering competing systems and continuing challenges of functionality and interoperability – These challenges discourage medical groups from investing the necessary human and financial capital for fear of buying an expensive system that cannot survive as vendors go out of business, or public and private sector incentive program requirements change.
- The dynamics of health system reform itself – As group practices merge with one another, or affiliate with hospital systems, and those systems in turn merge, contract or otherwise affiliate with larger health systems, the technology platforms are constantly in flux. An EHR system adopted by a medical group in 2010 in cooperation with one hospital partner may soon be obsolete when the first partner is absorbed by another using a different system.

As a result, EHR implementation remains a work in process, and the need for continuing support, both financial and regulatory, remains as valid today as when the current safe harbor was adopted in 2006. Elimination of the sunset provision is the logical policy response to that need.

In further support of this request, MGMA respectfully requests the OIG to consider the following aspects of this particular sunset provision.

1. The sunset provision as finally adopted was not formally proposed for public comment.

When the OIG first suggested possible safe harbor protection for certain EHR support arrangements in October of 2005, it was in conjunction with its rule-making to provide a new safe harbor for e-prescribing support arrangements. That rule-making provided specific regulatory text only for what became 42 C.F.R. § 1001.952(x) for e-prescribing, and not for what became 42 C.F.R. § 1001.952 (y). Instead, the OIG provided a more general outline for two EHR safe harbors, one to deal with systems prior to certification of interoperability, and a second to deal with support arrangements in a post certification environment.

In outlining these two proposals, the OIG suggested that only the first would sunset, but not the second. 70 Fed. Reg. 59,015-27 (Oct. 11, 2005). Then, at the final rule stage, the OIG
adopted only one EHR safe harbor for a post certification environment, and added to that option a sunset provision which it had not proposed. 71 Fed. Reg. 45,110-37 (Aug. 8, 2006). As a result, neither MGMA nor any other interested stakeholder was afforded the opportunity to comment on the specific provision that was ultimately adopted.

2. The rationale for the sunset provision was overly optimistic.

In support of the sunset concept adopted, the OIG assumed that the need for the EHR safe harbor should “diminish substantially over time” as EHRs became a “standard and expected part of medical practice,” and as physicians began to “realize the economic benefits from increased efficiencies and quality of care.” Id. at 45,133.

With the admitted benefit of hindsight, MGMA submits that these assumptions have proven overly optimistic. While MGMA still believes that EHRs will ultimately improve clinical care, we are concerned about the relatively slow pace of adoption, especially in smaller clinical settings. It is clear that for many practices, these high cost systems remain a burden to finance, particularly given the other cost pressures group practices face. Thus, while EHR adoption is on the rise, the technology is still not affordable for many groups.

3. The specific sunset date adopted did not relate to any heightened risk of fraud and abuse

In explaining its rationale for adopting a sunset provision, the OIG stated that “the balance between promoting health information technology and preventing fraud and abuse” would change over time. Id. Perhaps this will still be the case at some point in the future, but there is no reason to believe that Dec. 31 marks a turning point in this regard. Nothing in the original rule-making identified any factors that would lead to a heightened risk of fraud and abuse at the end of this year. In fact, it appears that this date was selected merely to conform to a Presidential “Health Information Technology Plan” adopted back in 2004. Id. In retrospect, that “Plan” has proven more aspirational than operational, and much work remains to be done to achieve its goals.

Significantly, MGMA is aware of no data to suggest that the EHR safe harbor has been abused in any way, or to suggest that it will suddenly be abused if it is extended. The safe harbor has its own built-in protections against its indiscriminate use, namely its failure to include protection for supported hardware purchases, and the requirement for physician cost-sharing even in software and training costs. There is simply nothing of which MGMA is aware to suggest that hospitals or others are lavishing financial support on physician practices as a disguised means of rewarding practices for referral arrangements. On the contrary, many of the same factors referenced above that have made group practices wary of rapid EHR implementation (high cost and technological uncertainty) have made potential hospital supporters similarly wary.

MGMA respectfully requests that the OIG use its authority to remove the current sunset provision in 42 C.F.R. § 1001.952 (y)(13). The safe harbor has proven to be an important factor in encouraging physicians to adopt EHRs. In addition, hospital donations to practices
have raised potential concerns about patient data “ownership.” We further urge the OIG, in conjunction with the Centers for Medicare & Medicaid Services, to provide guidance and education to physician practices and hospitals on addressing the issue of data ownership of patient information on donated EHRs. This would help allay concerns and further encourage these hospital-practice partnerships.

We appreciate the opportunity to provide these comments in response to the OIG’s solicitation. Should you or your staff have any questions concerning these matters, please contact Anders Gilberg, senior vice president, at 202.293.3450 or agilberg@mgma.org.

Sincerely,

Susan Turney, MD, MS, FACMPE, FACP
President and CEO