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October 26, 2018

Daniel R. Levinson, JD
Inspector General
US Department of Health and Human Services
Cohen Building, Room 5513
330 Independence Avenue, SW
Washington, DC 20201

Dear Mr. Levinson:

On behalf of the Healthcare Information and Management Systems Society (HIMSS), I am pleased to provide comments to the Department of Health and Human Services Office of the Inspector General (HHS-OIG) in response to the Medicare and State Health Care Programs: Fraud and Abuse; Request for Information Regarding the Anti-Kickback Statute and Beneficiary Inducements CMP. HIMSS appreciates the opportunity to leverage our members' expertise in offering feedback on this request for information (RFI), and we look forward to continued dialogue with HHS-OIG on this and other ways to remove potential government obstacles to care coordination such that we can continue to work to transform the healthcare system into one that better pays for value together.

As a mission driven non-profit, HIMSS offers a unique depth and breadth of expertise in health innovation, public policy, workforce development, research, and analytics to advise global leaders, stakeholders, and influencers on best practices in health information and technology. Through our innovation companies, HIMSS delivers key insights, education, and engaging events to healthcare providers, governments, and market suppliers, ensuring they have the right information at the point of decision.

As an association, HIMSS encompasses more than 73,000 individual members and 655 corporate members. We partner with hundreds of providers, academic institutions, and health services organizations on strategic initiatives that leverage innovative information and technology. Together, we work to improve health, access, as well as the quality and cost-effectiveness of healthcare. Headquartered in Chicago, Illinois, HIMSS serves the global health information and technology communities with focused operations across North America, Europe, United Kingdom, the Middle East, and Asia Pacific.

HIMSS supports the HHS-OIG's efforts to address regulatory provisions that may act as barriers to coordinated care or value-based care. As the Department and the entire stakeholder community continue to work to transform the health care system into one that does a better job paying for

value, facilitating care coordination becomes even more paramount. We want the regulatory oversight system to create a balance between additional flexibilities for stakeholders to provide efficient, well-coordinated, patient-centered care with protections against the harms caused by fraud and abuse.

For our public comment, HIMSS offers the following thoughts and recommendations on how HHS OIG may want to proceed in its review of modifying current Anti-Kickback Statute Safe Harbors as well as exploring additional exceptions:

Support for a Cybersecurity Safe Harbor Allowing Expanded Sharing of Related Items and Services

HIMSS looks to HHS-OIG to provide a Safe Harbor for donating or subsidizing cybersecurity related items and services to providers and others with whom information is shared. We echo the concerns noted in the June 2017 HHS Cybersecurity Task Force Report that, under the current physician self-referral law and Anti-Kickback Statute, cybersecurity vulnerabilities exist due to the legal prohibition on larger healthcare organizations helping smaller organizations and physician practices to purchase cybersecurity software, training, hardware, and operational services.

Because cybersecurity is so dependent on all the players in the networked industry, even organizations that put robust cybersecurity policies and software in place remain vulnerable due to connections with less-secure providers. Therefore, the HHS Task Force asked Congress to amend the Physician Self-Referral Law and Anti-Kickback Statute to allow healthcare organizations to help physicians implement cybersecurity software, along the lines of what they have done with electronic health records (EHRs).

HIMSS requests an exception to the Statute to allow for the subsidizing of cybersecurity needs such as software, hardware, training, and tools for cybersecurity risk identification as well as threat assessment. Although this exception would be very beneficial, we recognize that having the right tools is not enough; updates to the Safe Harbors should also make exceptions for operational support such as IT assistance and other skilled services to aid smaller organizations with deployment and maintenance of these cybersecurity solutions.

It is important to emphasize that cybersecurity is also a patient safety issue, and a robust cybersecurity program reinforces the push to greater data exchange and the shift to value-based care delivery and healthcare transformation. Overall, using additional Safe Harbors to build an expanded cybersecurity program furthers key health system-wide public policy objectives.

Update the Telehealth Safe Harbor to Correspond to Current Initiatives from the Centers for Medicare & Medicaid Services (CMS)

HIMSS is supportive of the greater use of telehealth by practitioners and asks that the Telehealth Safe Harbor be re-examined to echo the changes that CMS has made to expand telehealth coverage provisions and reduce the restrictions placed on telehealth providers. The Safe Harbor should be updated beyond Medicare patients with end-stage renal disease (ESRD) on home dialysis to

facilitate the use of telehealth across more clinical conditions and to allow for the provision of telehealth care outside of the previous limitations on geography and provider setting.

Over the past two years, CMS has taken a much more expansive view of telehealth and added several new Medicare codes to the list of telehealth services, including codes for Health Risk Assessment and Care Planning for Chronic Care Management. In the 2019 Physician Fee Schedule Proposed Rule, CMS also offered Medicare coverage for new telehealth services on store-and-forward technologies and brief virtual check-ins, as well as new remote patient monitoring (RPM) codes that expand coverage, and include a code for the initial set-up and patient education associated with an RPM device.

Overall, CMS is looking at additional steps that the agency could take to expand access to telehealth services even further within its current statutory authority and pay appropriately for services that take full advantage of communication technologies. The Safe Harbor should correspond to the approach that CMS has taken for a much more open perspective on paying for telehealth-related services and equipment.

Moreover, HHS-OIG could also go beyond additional codes and clinical conditions to look at broader Safe Harbors that provide for telehealth services and equipment without defining both eligible originating sites (the location of the beneficiary) and the distant site practitioners who may furnish and bill for telehealth services (originating sites are limited both by geography and provider setting).

As discussed in a HIMSS-Personal Connected Health Alliance Letter to the Federal Communications Commission from February 2018, trends suggest that underserved and medically vulnerable populations across the country are falling behind when it comes to the availability of high-quality healthcare. By improving the healthcare provider access to modern communications services in underserved and medically vulnerable populations, an additional Safe Harbor could help overcome some of the obstacles to healthcare delivery faced by these communities. Greater access to telehealth services in these underserved and medically vulnerable areas through expanded Safe Harbors will help contribute to better patient outcomes as well as comprehensive healthcare transformation efforts.

Maintain the Current EHR Safe Harbor, With Special Attention to a Carve-Out for Specific Segments of Providers and Interoperability Issues

HIMSS strongly supports the continuation of the current Statute's EHR Safe Harbor to ensure that more clinicians have access to the latest technology and can utilize that technology in the push to value-based care delivery. EHRs and other health technologies are designed to improve care and ultimately improve health as well as help streamline the extra layer of unnecessary effort that regulatory requirements often demand. Greater use of EHRs and other innovative technologies allow clinicians to better serve patients and help alleviate additional burdens they may face to meet regulatory and documentation requirements.

This more advanced information and technology infrastructure will increase the focus on the patient and reinforce better decisions and shared decision-making, and improve the efficiency of

normal healthcare operations, which includes reducing or eliminating burden. All clinicians should be able to take advantage of this Safe Harbor and access technology to help make the right information more accessible at the right time so it is more meaningful and impactful to patients as well as providers.

HHS-OIG should review whether reconsideration of the Safe Harbor's mandatory 15 percent contribution is warranted for specific segments of providers. HIMSS endorses the idea that providers in federally-designated Health Professional Shortage Areas (HPSAs), and from small and underserved and medically vulnerable populations practices should be able to take advantage of the Safe Harbor without incurring the 15 percent contribution. As these providers are serving our nation's most geographically isolated, economically or medically vulnerable populations, these special circumstances should allow affected providers to receive these tools for free or have a lower overall percentage contribution.

In addition, the interoperability conditions included in the EHR Safe Harbor should be updated given the current implementation of the 21st Century Cures Act (Public Law 114-255) and other work underway at the HHS Office of the National Coordinator for Health IT (ONC) and CMS to promote greater interoperability across the care continuum. Rules and guidance documents under development on the Trusted Exchange Framework and Common Agreement, information blocking, and the MyHealthEData Initiative will likely (when finalized) serve as appropriate proxies for whether EHR software is deemed interoperable and data is being shared. HHS-OIG's EHR Safe Harbor regulations should support the work of ONC and CMS and contribute to an environment where more data is being shared across the entire community.

Support for the Provision of Beneficiary Incentives that Lead to More Patient Engagement Opportunities

In our recent Medicare Shared Savings Program (MSSP) Proposed Rule Public Comment Letter, HIMSS expressed support for the MSSP Proposed Rule's focus on patient engagement as an important part of motivating and encouraging more active participation by beneficiaries in their health care. Health information and technology tools play a critical role in advancing this paradigm. We believe Accountable Care Organizations (ACOs) that engage beneficiaries in the management of their health care may achieve better outcomes and experience greater success in the Shared Savings Program and support movement toward our goal of broader healthcare transformation.

Outside of MSSP, HIMSS is supportive of the more extensive use of Safe Harbors focused on incentives that encourage more beneficiary engagement and participation in achieving better outcomes. We would like to see these arrangements flourish between all providers and beneficiaries in all federal health care programs, including Medicare and Medicaid. Incentives should be focused on beneficiaries that are taking steps to implement or comply with a practitioner's care plan, including for medication adherence and medication management. HIMSS is particularly interested in incentives focused on the mitigation of a chronic disease or condition, or chronic disease self-management, as these areas may be best-suited for greater patient engagement and intervention, as well as a broader healthcare system impact.

These incentives should emphasize in-kind items or services to beneficiaries if there is a reasonable connection between the items or services and the medical care of the beneficiary, and the items or services are preventive care items or services, or advance a clinical goal of the beneficiary, including: adherence to a treatment regime; vouchers/memberships to wellness programs or classes; or, remote monitoring technologies for facilitating home-based care.

As previously discussed, HHS-OIG should work with their partner agencies across the federal government to explore whether incentives should also focus specifically on HPSAs, or underserved and medically vulnerable population areas which would help outreach efforts to our nation's most geographically isolated, economically or medically vulnerable populations, and continue to fully integrate these populations into efforts to achieve better patient outcomes.

HIMSS is committed to be being a valuable and collaborative resource to HHS-OIG and the entire healthcare community in the continuing push to transform the healthcare system into one that better pays for value. We welcome the opportunity to meet with you and your team to discuss our comments in more depth. Please do not hesitate to contact Jeff Coughlin, Senior Director, Federal & State Affairs, at 703.562.8824, or Eli Fleet, Director, Federal Affairs, at 703.562.8834, with questions or for more information.

Thank you for your consideration.

Sincerely,

Harold F. Wolf III, FHIMSS
President & CEO