ConnectedHealth

August 24, 2018

Administrator Seema Verma
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, District of Columbia 20201

RE: *Medicare Program; Request for Information Regarding the Physician Self-Referral Law* (CMS-1720-NC)

Dear Administrator Verma:

The Connected Health Initiative (CHI) appreciates the opportunity to respond to the Centers for Medicare and Medicaid Services (CMS) request for information on how to address undue regulatory impact and burden of the physician self-referral law (Section 1877 of the Social Security Act, known as the "Stark Law").[1] We appreciate the Administration's work to remove and mitigate unnecessary regulatory burdens in the healthcare context, as well as its commitment to dismantling barriers to value-based care transformation, all while also protecting the integrity of the Medicare program.

The Connected Health Initiative (CHI) is the leading effort by stakeholders across the connected health ecosystem to clarify outdated health regulations, encourage the use of digital health innovations, and support an environment in which patients and consumers can see improvements in their health. We seek essential policy changes that will enable all Americans to realize the benefits of an information and communications technology-enabled American healthcare system. For more information, see www.connectedhi.com.

[1] Centers for Medicare and Medicaid Services, *Medicare Program; Request for Information Regarding the Physician Self-Referral Law*, 83 FR 29524 (June 25, 2018).

Data and evidence from a variety of use cases continue to demonstrate how the connected health technologies available today improve patient care, prevent hospitalizations, reduce complications, and improve patient engagement, particularly for the chronically ill. These tools, including wireless health products, mobile medical device data systems, telemonitoring-converged medical devices, and cloud-based patient portals, are revolutionizing American healthcare by securely enabling the exchange of health information and incorporating patient-generated health data (PGHD) into the continuum of care. We urge CMS' review of CHI's aggregation of numerous studies that demonstrate the improved outcomes and reduced costs associated with greater use of connected health innovations.[2]

The healthcare sector has evolved since the enactment of the Stark Law in 1989. We agree with CMS that the Stark Law is an important anti-fraud protection for Medicare, however, it is out of date, may present barriers to innovation, and considerations for new exceptions to the law are needed. We urge creation of Stark Law exceptions that will responsibly facilitate the greater uptake of connected health innovations – be they hardware, software, or a combination of the two – throughout the continuum of care, including for Accountable Care Organizations. We support extension of, or creation of, exceptions for the following:

- Extension of the donation exemption (scheduled to end in 2021) for interoperable technology and training, along with an expansion of this exemption to allow for donations aimed to improve the exchange of health data through innovative application programming interfaces (APIs) and other tools. We believe permitting such donations will assist smaller practices seeking to advance value-based care through the use of connected health technologies, but that face resource constraints.
- Creating an exemption for the donation or subsidizing of cybersecurity technologies (hardware, software, or some combination of the two) and/or services. Like other critical infrastructure sectors, the healthcare sector faces increasing cyber-based attacks, both in quantity and in sophistication, which ultimately places patients at greater risk. We urge CMS to use any means available to improve the cybersecurity risk posture of the healthcare sector as a whole, including through exceptions to the Stark Law. If CMS does not have the ability to create such a Stark exception, we encourage CMS to seek the statutory authority from Congress to create an exception to allow for the donation or subsidy of cybersecurity technology. CHI notes such a step has been endorsed by the Health Care Industry Cybersecurity Industry (HCIC) Task Force Report,[3] written pursuant to the Cybersecurity Information Sharing Act of 2015.

[2] This CHI resource is publicly accessible at https://bit.ly/2MblRou.

[3] Health Care Industry Cybersecurity Industry (HCIC) Task Force Report (June 2017) at p. 35, *available at* https://www.phe.gov/Preparedness/planning/CyberTF/Documents/report2017.pdf.

CHI believes taking the above specific steps will further assist CMS in realizing a successful Merit-based Incentive Payment System (MIPS) as well as alternative payment models (APMs) envisioned by Congress in the Medicare and CHIP Reauthorization Act of 2015 and a successful Promoting Interoperability program. Eased access to connected health innovations will assist satisfying the new risk assessments providers will need to undergo.

Finally, CHI notes its linked belief that the Department of Health and Human Services' Office of the Inspector General should provide clarification on questions regarding anti-kickback laws to reflect realistic engagement program requirements. Such issues include ensuring that giving patients a device (e.g., a tablet) to communicate with a care team is not considered patient inducement; or that providing physician platforms for telemedicine is not violating the anti-kickback statute. We have raised our views regarding the anti-kickback statute previously in more detail,[4] and urge for their careful consideration by CMS.

Sincerely,

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[4] CHI Letter to Presidential Innovation Fellow Gil Alterovitz (May 10, 2018), *available at* https://bit.ly/2P1XCql.