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June 16, 2014

The Honorable Joe Pitts
Chairman
House Committee on Energy and Commerce
Subcommittee on Health
United States House of Representatives
Washington, D.C. 20515

The Honorable Frank Pallone
Ranking Member
House Committee on Energy and Commerce
Subcommittee on Health
United States House of Representatives
Washington, D.C. 20515

Dear Chairman Pitts and Ranking Member Pallone:

As health systems that have deployed telehealth technology and engaged in the provision of telemedicine in numerous states across the country, we have come together to respond to your request for information from the public on how Congress can encourage and support the use of technology to advance our nation's healthcare system. We are familiar with the financial and operational challenges associated with delivering these services on a sustainable basis and believe the actions outlined below are steps Congress can take to foster the use of this important technology.

As the Committee heard at the May 1, 2014 hearing, there are many barriers to telemedicine. We believe that removing some of these barriers requires balancing the competing interests of participants in healthcare in favor of increased access and revising anti-fraud measures in circumstances where the risks of potential fraud are significantly outweighed by the benefits to patients and the community. Congress can make such progress through three adjustments to existing laws that will provide a better environment for telemedicine in a measured and prudent manner. These three adjustments are:

1. Extend the Stark Law exception and Anti-Kickback safe harbor allowing a hospital or other provider to donate items and services consisting of electronic health records

systems to physicians and the related IRS guidance clarifying that the provision of such equipment would not constitute impermissible private benefit or inurement to also allow the donation of telehealth items and services;

2. Remove all geographic restrictions on the traditional Medicare coverage of telehealth services, require comparable coverage in Medicaid State plans, and require comparable coverage for Medicare Part C plans; and
3. Add an exclusion under the Civil Monetary Penalties law to expressly allow hospitals and other providers to make available to patients home health monitoring equipment, services, and similar technology at the time of discharge and at no cost to the patient or payers in an effort to reduce readmissions and foster better post-hospital care.

Extension of EHR Donation Regulations.

CMS and HHS have promulgated a Stark Law exception¹ and Anti-Kickback Statute safe-harbor² (collectively "EHR Donation Regulations") that permit the donation of 85% of the cost of items and services necessary and predominantly used for an EHR. The EHR Donation Regulations are limited to items and services that are necessary for an EHR. We believe the EHR Donation Regulations should be expanded to include the provision of telehealth-related items and services. In addition, we believe the IRS guidance issued in relation to the EHR Donation Regulations should also be expanded to include the donation of items and services associated with the provision of telemedicine services.

Financial arrangements between healthcare entities and physicians are subject to a significant amount of regulation and scrutiny. The federal Stark Law provides that unless an exception is met where a physician has a direct or indirect financial relationship with an entity (such as a hospital or clinical laboratory), the physician may not refer to the entity for the provision of certain "designated health services" ("DHS") payable under Medicare or Medicaid. The provision of telehealth equipment, unless excepted from the definition of remuneration, could create a financial relationship under the Stark Law and, without an extension of the EHR Donation Regulations, be prohibited. While other existing exceptions may in some settings already be available, establishing a clear and specific exception will increase certainty for the industry and remove perceived barriers.

The federal Anti-Kickback Statute ("AKS") makes it a felony to knowingly and willfully offer, pay, solicit, or receive remuneration, directly or indirectly, in order to induce business that is reimbursable under any federal health care program. The law is intent-based, and courts have taken a broad interpretation of its scope, holding that if just *one purpose* of a payment is to induce referrals, the arrangement violates the AKS.³ Similar to the Stark Law in its penalties, healthcare providers are hesitant to engage in activities that do not squarely fall within the

¹ Medicare Program; Physicians' Referrals to Health Care Entities with Which They Have Financial Relationships; Exceptions for Certain Electronic Prescribing and Electronic Health Records Arrangements ("Exception"), 71 Fed. Reg. 45140.

² Medicare and State Health Care Programs: Safe Harbors for Certain Electronic Prescribing and Electronic Health Records Arrangements Under the Anti-Kickback Statute ("Safe Harbor"), 71 Fed. Reg. 4511.

³ *U.S. v. Greber*, 760 F.2d 68 (3d Cir. 1985).

bounds of a safe harbor to the AKS. In order to avoid this uncertainty, a safe harbor allowing the provision of non-monetary remuneration in the form of items and services necessary and related to provide telemedicine services should be promulgated.

Removal of Geographic Limitations on Coverage of Telemedicine Services.

The Medicare program covers and pays for telehealth services in certain limited circumstances. Coverage and payment is limited depending on the type of services provided, geographic location, type of institution delivering the services, and type of health provider.⁴ The geographic limitation currently requires that the patient be located in a rural Health Professional Shortage Area ("HPSA") or county outside of a Metropolitan Statistical Area ("MSA") (i.e., a "rural" area). We believe the limitation of geographic areas for Medicare reimbursement should be removed, and the coverage for other federally related health plans should also be expressly expanded, for the following reasons.

In some instances, it can mean lower cost and better access for patients to be treated via telemedicine within an urban area or rural area not meeting the narrow requirements for the current Medicare exception. For example, due to extreme winter weather conditions, it may not be advisable for an elderly patient to travel with certain health conditions. The risk of harm to the patient from extreme cold or ice exists, to a similar extent, with respect to a patient located in urban or rural areas. Likewise, transportation across certain metropolitan areas to access specialists may not be a necessary or efficient use of the federal health care system's resources when the same standard of care can be met through the use of telemedicine services without Medicare incurring the cost of patient transport.

Certain Core Based Statistical Areas ("CBSAs") are geographically large and may extend to include both dense urban areas as well as more sparsely populated communities. For provider locations in these sparsely populated communities, including certain hospitals, there may be a real shortage of local and direct specialty coverage, even though those specialties may be available in more densely populated portions of the CBSA. Telemedicine coverage in these settings would allow patients to be treated and remain closer to home, avoiding transportation costs and allowing the patients to receive greater access to care in the communities in which they live. Finally, in some instances, the convenience of telemedicine services can encourage patients to seek treatment earlier in the disease process when treatment is less expensive and outcomes are improved.

Exclusion from the Civil Monetary Penalties.

Congress has clearly expressed its desire for healthcare providers to deliver care in a manner that reduces the number of patients that must be readmitted to the hospital shortly after discharge. Specifically, Section 3025 of the Affordable Care Act established the Hospital Readmissions Reduction Program, which requires CMS to reduce payments to IPPS hospitals with excess readmissions. Our experience with the use of telemedicine equipment to monitor patients post-discharge has shown remarkable promise to reduce instances of readmission. However, under

⁴ Medicare Claims Processing Manual, CMS Pub. 100-04, §190.2.

existing law, it is uncertain whether a hospital can provide this monitoring equipment to a patient without violating federal fraud and abuse law.

The improvement and better coordination and delivery of post-acute care is becoming a recognized area where improvement is needed, and various telemedicine technologies are being created to facilitate and improve the care in these settings. Similar to the concerns regarding technology relating to readmission, it is also uncertain just when a hospital or other provider can avail patients of this technology to improve the delivery of post-acute care, without potentially violating the law.

The Civil Monetary Penalties ("CMP") law provides that any person that offers to transfer remuneration to any individual eligible for benefits under the federal healthcare programs or state healthcare programs that such person knows or should know is likely to influence such individual to order or receive from a particular provider, practitioner, or supplier any item or service for which payment may be made under the programs, shall be subject to the penalties set forth under the law.⁵ Remuneration under the CMP includes the provision of items and services for free or for other than fair market value. Thus, the provision of telemedicine monitoring equipment by a hospital to a patient on discharge, and other equipment and technology relating to post-acute care, could be deemed to be impermissible remuneration under existing law.

We believe Congress should revise the definition of remuneration under the CMP to explicitly exclude the provision of items and services by a provider to a patient at discharge in order to guard against readmission and monitor patient vitals and compliance with recovery instructions and other post-acute care coordination activities for a period of up to 90 days from discharge from a hospital. Such an exclusion from the definition of remuneration would allow hospitals and other healthcare providers to provide advanced technology to patients to reduce readmissions, improve post-acute care, encourage innovation, and improve outcomes in our health system. While certain aspects of this technology may, over time, evolve to be the types of items and services that are recognized and paid by third party payers as part of health plan coverage (which much of it should), allowing a safe place for providers to decide to cover the costs of this technology in the interim, without risk of legal scrutiny, would promote the delivery and receipt of better care.

We greatly appreciate this opportunity to provide information on how Congress can improve the legal and regulatory environment to facilitate the adoption of telehealth technology and provision of telemedicine services. We look forward to working with you as the Committee looks for new ideas that will foster and promote this important method of delivering quality healthcare to patients everywhere.

⁵ Sec. 1128A [42 U.S.C. 1320a-7a] (a)(5).

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A handwritten signature in black ink, appearing to read "John F. Williams III". The signature is fluid and cursive, with a prominent "III" at the end.

John F. Williams