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CMS ADDS NEW HARDSHIP EXEMPTIONS FROM E-PRESCRIBING REQUIREMENTS

On September 6, 2011, the Centers for Medicare & Medicaid Services (CMS) released additional hardship exemption categories (New Hardship Exemptions) for the Electronic Prescribing Incentive Program (eRx Program) and extended the deadline for requesting a Hardship Exemption (defined below). Under the eRx Program, CMS offers financial incentives to certain Medicare-participating health care providers, including physicians, allied health providers, and other health care practitioners (collectively, Eligible Professionals) who successfully implement and use an electronic prescribing system (that is, a successful user). Eligible Professionals can choose to participate in the eRx Program by reporting certain measures to CMS. Participation in the eRx Program is limited to Eligible Professionals who (1) have prescribing authority, (2) use a qualified electronic prescribing system, and (3) have at least 10 percent of total Medicare Part B physician fee schedule charges from a list of service codes provided by CMS (eRx Codes List). In addition, certain group practices may elect to participate in the eRx Program.

Under the 2011 Physician Fee Schedule (the 2011 PFS), an Eligible Professional is deemed to be a successful user of an electronic prescribing system if such Eligible Professional submitted at least 10 electronic prescriptions between January 1, 2011, and July 30, 2011. Whether a group practice is considered a successful user of an electronic prescribing system depends upon (1) the size of such group practice and (2) the number of electronic prescriptions reported. The threshold for successful electronic prescribing ranges from 75 to 2,500 electronic prescriptions generated by a group practice in 2011. Eligible Professionals and group practices classified as unsuccessful users of an electronic prescribing system in 2011 may be subject to a financial penalty in the form of reduced reimbursement from CMS for Medicare services beginning in January 2012 (a Payment Adjustment), unless an exemption is satisfied. An Eligible Professional may be subject to a Payment Adjustment even if such Eligible Professional does not elect to participate in the eRx Program. However, the 2011 PFS contains a number of exemptions to Payment Adjustments under the eRx Program (the PFS Exemptions). Pursuant to the 2011 PFS,

an Eligible Professional who is an unsuccessful user of an electronic prescribing system will not be subject to a Payment Adjustment in 2012 if such Eligible Professional is (a) not a physician, nurse practitioner, or physician assistant as of June 30, 2011, or (b) does not have at least one hundred claims for Medicare Part B services from the eRx Codes List. In addition, any Eligible Professional or group practice that has less than 10 percent of its total charges from services on the eRx Codes List will not be subject to a Payment Adjustment in 2012. The PFS Exemptions are subject to change in the 2012 Physician Fee Schedule.

In addition to the PFS Exemptions, an Eligible Professional or group practice that is considered to be an unsuccessful user of an electronic prescribing system may avoid a Payment Adjustment if CMS determines that compliance with the eRx Program would cause a significant hardship to such Eligible Professional or group practice and, therefore, qualifies for a hardship exemption (Hardship Exemption). The 2011 PFS already contained two Hardship Exemptions (prior to the New Hardship Exemptions) that apply to Eligible Professionals or group practices in (1) a rural area with limited internet access and (2) an area with limited pharmacies available for electronic prescribing. The New Hardship Exemptions outlined below will provide Eligible Professionals and group practices with additional opportunities to avoid Payment Adjustments in 2012.

The New Hardship Exemptions include the following:

- Eligible Professionals and group practices who have registered to participate in a Medicare or Medicaid Electronic Health Record (EHR) Incentive Program and have adopted certified EHR technology for those Eligible Professionals and group practices that delayed adopting the technology necessary because they chose to participate in the eRx Program.

- Eligible Professionals or group practices that are not able to electronically prescribe due to local, state, or federal laws that limit electronic prescribing (for example, laws that prevent practitioners from submitting electronic prescriptions for narcotics).

- Eligible Professionals with limited prescribing activity, such as nurse practitioners who do not use their own National Provider Identifier (NPI) to write prescriptions.

- Eligible Professionals or group practices who have an electronic prescribing system and electronically prescribe but do not routinely prescribe medications, such as surgeons.

CMS determines whether an Eligible Professional or a group practice satisfies a Hardship Exemption and whether such determination applies retroactively. CMS has adopted a new process for Eligible Professionals and group practices when requesting a Hardship Exemption (Hardship Exemption Request). Eligible Professionals must complete an online Hardship Exemption Request using a new CMS website. Group practices, however, must submit a Hardship Exemption Request via a mailed letter to CMS that contains the following information:

- Taxpayer Identification Number, NPI, name, mailing address, and e-mail address of all applicable Eligible Professionals within the group practice

- Hardship Exemption(s) that apply to the group practice

- Statement justifying the application of such Hardship Exemption(s)

- Attestation of the accuracy of the information submitted to CMS

Eligible Professionals and group practices seeking a Hardship Exemption must submit their Hardship Exemption Request no later than November 1, 2011.

HHS PROPOSES DIRECT PATIENT ACCESS TO LABORATORY TEST RESULTS

On September 14, 2011, the Department of Health & Human Services (HHS) published a proposed rule that would allow patients to directly access their laboratory test result reports from the laboratory (Proposed Rule). The Proposed Rule was drafted to support (1) the anticipated widespread adoption of electronic health records (EHR) and (2) the recognition of health care reform concepts such as individualized medicine and a more active individual role in health care decisions and treatment. The Proposed Rule would amend regulations that currently impose restrictions on patient access to laboratory test result reports pursuant to the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Access the Proposed Rule here.

CLIA provides rules for certain laboratories that perform testing on human specimens for the purpose of providing information for diagnosis or treatment. Under current CLIA regulations, laboratories subject to CLIA may disclose laboratory test results to (1) an authorized person, (that is, an individual authorized under state law to order or receive test results), (2) the individual responsible for using the test results for treatment purposes, and (3) a referring laboratory.

HIPAA provides standards for the privacy and security of individually identifiable health information, which includes right of access for patients to inspect and obtain a copy of their protected health information (PHI). A laboratory is subject to HIPAA if it engages in certain electronic transactions as defined by HIPAA. That said, a patient's right of access to inspect and obtain a copy of PHI does not currently extend to health records maintained by laboratories that are subject to CLIA or laboratories exempt under CLIA.

The practical effects of the Proposed Rule on a laboratory, and such laboratory's patients, depend upon how the laboratory is categorized. Laboratories subject to HIPAA must disclose PHI (that is, laboratory test result reports) directly to the patient. Laboratories that are not subject to HIPAA, but otherwise subject to or certified under CLIA, have the option of disclosing laboratory test results to individuals upon request.

Laboratories required to comply with the Proposed Rule are required to provide individuals with access to their PHI in the form or format requested by the individual if it is producible in such format. In addition, such laboratories must satisfy HIPAA's verification requirement prior to releasing reports by verifying the identity of the person/entity requesting the disclosure of PHI and the authority of such person/entity to receive such PHI. Laboratories are permitted to charge a reasonable fee to provide the PHI.

The Proposed Rule's amendments to the HIPAA regulations preempt any "contrary" state laws. A number of states, such as Rhode Island, prohibit laboratories from releasing laboratory test result reports directly to patients. Other states, such as Connecticut and Massachusetts, allow the release of laboratory test report results directly to patients when the ordering provider gives written consent. Because it is impossible for laboratories in these states to comply with both HIPAA's right of access and applicable state laws, the revised HIPAA Privacy Rule will become the prevailing law with which these laboratories must comply.

CMS is soliciting comments on the Proposed Rule. Such comments must be received by CMS by November 14, 2011.

OIG ISSUES ADVISORY OPINION: PROPOSED TELENEUROLOGY ARRANGEMENT NOT SUBJECT TO SANCTIONS

On September 6, 2011, the Office of the Inspector General (OIG) issued an Advisory Opinion (Advisory Opinion) regarding a health system's (Requestor) proposal to provide teleneurology services to community hospitals (Proposed Arrangement). The OIG ultimately concluded that, while the Proposed Arrangement had the *potential* to generate prohibited remuneration under the Anti-kickback Statute (AKS), the Proposed Arrangement had sufficient safeguards to prevent a violation of AKS from occurring.

Proposed Arrangement

The Requestor operates a hospital that offers neurological care. Local community hospitals that do not have the medical resources to treat acute stroke and other neurological emergencies frequently transfer suspected stroke patients to hospitals with comprehensive stroke centers. To avoid delays in treatment, comprehensive stroke centers often offer community hospitals access to their stroke neurologists for telephone consultations 24 hours per day. These consultations are frequently informal and of limited quality. Under the Proposed Arrangement, the Requestor would provide community hospitals (Participating Hospitals) with (1) neuro emergency telemedicine equipment; (2) neuro emergency clinical consultations; (3) acceptance of neuro emergency transfers; and (4) neuro emergency clinical protocols, training, and medical education (collectively, the Program).

The Requestor, at the Requestor's expense, would install teleneurology equipment within the Emergency Department at each Participating Hospital, which would enable the Requestor's neurologists to consult, in real time, with the Participating Hospitals' emergency medicine physicians. Teleneurology equipment maintenance, support, upgrades, and support services would also be provided by the Requestor. Participating Hospitals would be required to install and maintain at least one computed tomography (CT) scanner capable of transmitting CT scan images to a remote server. While marketing activities would not be required under the Program, the Requestor and Participating Hospitals would be able to use each other's trademarks and service marks for limited marketing purposes.

The Program would initially be offered to community hospitals with which the Requestor has an existing clinical affiliation. The Requestor would also have the option of offering the Program to community hospitals in the Requestor's service area with which it is not currently affiliated. Such offers would be based on access-to-care considerations.

The Requestor proposed entering into a two-year written agreement (Agreement) with each Participating Hospital. The Agreement would contain an exclusivity requirement that restricts a Participating Hospital from using any other teleneurology service for the two-year term of the Agreement. However, the exclusivity requirement would not (1) restrict physicians at the Participating Hospitals from consulting with stroke specialists outside of the Requestor's network, (2) require either party to refer patients to the other party, or (3) restrict the physicians or patients from requesting a transfer to a stroke center other than the Requestor's stroke center. The Requestor certified to the OIG that neither the continued transfer of stroke patients to the Requestor nor the value or volume of any other business generated between the parties would be a condition of participation in the Program.

OIG Findings

The AKS prohibits any person from soliciting or receiving any direct or indirect remuneration in exchange for referrals or ordering of items or services reimbursable by a federal health care program unless a safe harbor is satisfied.

The OIG concluded that the Proposed Arrangement would not satisfy the AKS safe harbor for personal services and management contracts because the Participating Hospitals' emergency physicians would use the Requestor's services on an unscheduled, as-needed basis. Despite the failure of the Proposed Arrangement to satisfy a safe harbor, the OIG found that the Proposed

Arrangement contained five factors that, in combination, significantly reduced the risk that remuneration provided under the Proposed Arrangement could be an improper payment for referrals. The five factors were as follows:

- The Participating Hospitals and their physicians would not be required or encouraged to refer their patients to the Requestor as a condition of participation in the Program, and the Participating Hospitals' emergency medicine physicians, at all times, would remain free to consult with other neurologists or refer their patients to a hospital other than the Requestor's hospital.

- Participation in the Program would initially be offered to clinically affiliated hospitals of the Requestor and participation would not be conditioned on the volume or value of a hospital's referrals to the Requestor or any business generated between the parties.

- While both the Requestor and the Participating Hospitals potentially benefit from the Proposed Arrangement, the primary beneficiaries would be patients of the Participating Hospitals.

- Neither the Requestor nor any Participating Hospital would be required to engage in marketing activities related to participation in the Program, and each party would be responsible for its own marketing costs.

- The Proposed Arrangement would be unlikely to result in increased costs to the federal health care programs because few consultations would be billable to Medicare, and the transfer of patients to certified stroke centers would decrease under the Proposed Arrangement, thereby reducing costs associated with neurological emergency care.

Although the OIG stressed that the Advisory Opinion is limited to the Requestor, the Advisory Opinion provides guidance for hospitals contemplating using teleneurology to deal with limited on-call neurological resources.

EXECUTIVE ORDER ADVANCES UNION RIGHTS FOR PERSONAL CARE ATTENDANTS IN CONNECTICUT

On September 21, 2011, Governor Malloy signed an executive order that advances workers' rights for personal care attendants and potentially lays the groundwork for them to organize and collectively bargain in Connecticut.

Executive Order No. 10 (Executive Order) requires the State to recognize an organization, that has been elected by personal care attendants who are paid through personal care assistance programs administered by the Department of Social Services (DSS) and the Department of Developmental Services (DDS) (collectively, Programs), as a majority representative (Majority Representative) for the purposes of entering into non-binding discussions with the Personal Care Attendant Workforce Council (defined below) regarding issues such as the quality, recruitment and retention of personal care attendants, as well as issues related to compensation, training, and professional development of personal care attendants. The Programs provide personal care assistance services to eligible adults who have chronic, severe, and permanent disabilities. The Executive Order requires a card check procedure for electing each Majority Representative, which means that secret ballot union elections are not permitted.

The Executive Order also establishes a Personal Care Attendant Quality Home Care Workforce Council (Personal Care Attendant Workforce Council) to ensure the quality of long-term personal home care. The Personal Care Attendant Workforce Council, a seven-member committee, will

consist of the Commissioner of Social Services, the Commissioner of Developmental Services, the healthcare advocate (or their respective designees), and four persons to be appointed by the Governor. The Personal Care Attendant Workforce Council is charged with studying issues related to improving the quality and accessibility of the Programs.

Additionally, the Executive Order establishes a working group, composed of five persons appointed by the Governor, to make recommendations to best enable the Majority Representative to bargain collectively the terms and conditions of the participation of personal care attendants in the Programs.

Pursuant to the Executive Order, if discussions involving the Majority Representative produce an understanding that requires legislation or rulemaking, such Majority Representative may make recommendations for legislation or rulemaking to (1) the appropriate state department or (2) the General Assembly; however, neither the appropriate department nor the General Assembly is required to affirmatively act on any such recommendations or proposals.

The Executive Order requires that the working group be established on or before October 1, 2011, and report on its recommendations and findings to the Governor no later than February 1, 2012.

If you have questions about any of these matters, contact a member of our Health Law Group.

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