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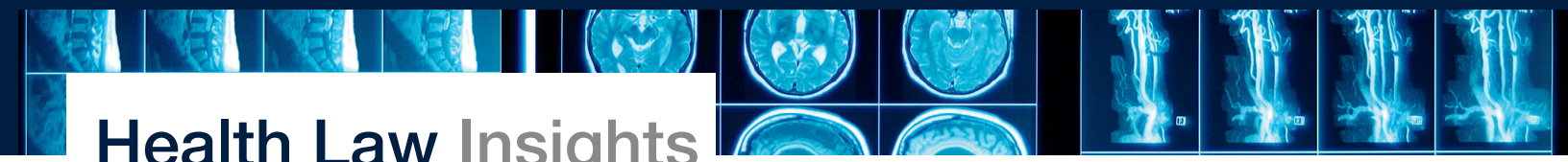

Health Law Insights

ISSUE | 3

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FEDERAL UPDATE

CMS Issues Final Rule Designed to Streamline Medicare Regulatory Requirements

The Centers for Medicare & Medicaid Services (CMS) issued a final rule to reduce unnecessary or overly burdensome requirements on health care providers. Multi-hospital systems may now have a unique medical staff for each hospital or a unified and integrated medical staff shared by multiple hospitals within the same system. If a unified and integrated medical staff is chosen, each hospital must demonstrate that it actively addresses its use of a unified system and integrated medical staff model by a vote of the medical staff of each hospital to participate in such model and the unified staff adopting integrated policies and procedures, among other requirements.

Additionally, subject to state law requirements and governing body discretion, hospitals have the option to appoint other categories of physicians and non-physician practitioners to their medical staffs. Moreover, hospitals may grant limited privileges to registered dietitians and qualified nutritionists to order patient diets directly.

Further, non-staff practitioners may order hospital outpatient services for their patients when authorized by the medical staff and as permitted by state law.

Also, it will no longer be required that a member of the medical staff sit on the hospital governing board. Instead, the governing board is required only to consult periodically throughout the year with the individual responsible for the organized medical staff of the hospital or his or her designee. For multi-hospital systems using a single governing body to oversee multiple hospitals within its system, the body will be required to consult directly with the individual responsible for the organized medical staff of each hospital within its system.

The rule also removes the direct supervision requirement for in-house preparation of radiopharmaceuticals, meaning a pharmacist or physician will no longer need to be present in the hospital for off-hour nuclear medicine tests.

Ambulatory surgical centers will now have fewer requirements to meet in order to provide radiology services that are integral to surgical services.

OIG Proposed Rules Would Boost Use of Civil Monetary Penalties and Toughen Exclusion Authority

The United States Department of Health and Human Services' (HHS) Office of Inspector General (OIG) has proposed a rule that would expand its use of civil monetary penalties (CMPs). Under the proposed rule, CMPs could now be imposed for:

- failing to provide the OIG with quick access to documents;
- ordering or prescribing medication or services while excluded from participation in federal health care programs;
- making false statements on enrollment applications to participate in federal health care programs;
- failing to report and return overpayments; and
- making a false statement that is part of a fraudulent claim.

CMPs could now also be imposed on Medicare Advantage and Medicare Part D organizations whose employees or contractors engaged in fraudulent activity, if they enroll someone without consent, if they transfer an enrollee to another plan without the enrollee's consent, if they transfer an enrollee to make a commission or if they fail to comply with marketing restrictions.

Additionally, the OIG seeks to clarify the primary factors that are used to determine the amount of a CMP. They are:

- nature of violation;
- degree of guilt by individual;
- prior offenses; and
- additional bad conduct.

The OIG proposes also to add a mitigating factor to the degree of guilt if the actor takes corrective actions.

Further, the OIG proposes to raise the claims-mitigating factor from $1,000 to $5,000.

Finally, the OIG has proposed a rule that would allow the OIG to now impose exclusions on actors for:

- convictions associated with the obstruction of an audit;
- failure to supply payment information to either Medicare or a state health care program; and
- making, or causing to be made, false statements on a provider application for participation in a federal health care program.

A United States district court ruled that a clinical laboratory's provision of free urine drug-screening cups that include testing strips to physicians might violate the Stark Law and the federal Anti-Kickback Statute (AKS).

CMS Updates Hospice Wage Index and Payment Rate

CMS proposes to raise payment rates and the wage index for hospice providers by 1.3% in Fiscal Year 2015. The proposed rule also requires hospice providers to file notices of termination/revocation within three days of a beneficiary's discharge or revocation unless the provider has already filed a final claim and to identify attending physicians on election forms.

Furthermore, hospice providers will now need to complete both cap determinations and subsequent remits within 150 days of cap determinations. Failure to do so will result in suspended payments. Finally, newly certified hospice providers receiving their CMS certification number on or after November 1, 2014, may be excluded from the quality reporting requirements for the Fiscal Year 2016 payment determination.

CMS is also seeking comment on the definitions of "terminal illnesses" and "related conditions" and the process and appeals for Medicare Part D payment for drugs and hospice coordination.

Free Urine-Testing Supplies Might Violate the Stark Law and the Federal Anti-Kickback Statute

A United States district court ruled that a clinical laboratory's provision of free urine drug-screening cups that include testing strips to physicians might violate the Stark Law and the federal Anti-Kickback Statute (AKS). Ameritox, Ltd., argued in a lawsuit that Millennium Laboratories, Inc., provided the cups to physicians for free in exchange for the physicians' agreement not to bill for the preliminary results obtained by the physician on the spot. Instead, the physicians would send the cups back to Millennium and Millennium would perform confirmation testing and bill for that test. The court held that no Stark Law exception applied and whether the cups constituted improper remuneration would need to be decided by a jury. The analysis would be the same for the application of the Stark Law and the AKS.

Proposed New ICD-10 Implementation Deadline

CMS has proposed October 1, 2015, as the new date for the International Classification of Diseases, 10th Revision (ICD-10), implementation deadline. The proposed rule also requested comments on how the ICD-10 transition will affect the hospital value-based performance payment program.

CMS Proposes Rule to Increase Payments to Inpatient Acute Care Hospitals

CMS has proposed to increase payments to inpatient acute care hospitals in Fiscal Year 2015 by 1.3%. The 1.3% figure is a net number, as it combines a 2.7% market basket increase, a 0.8% cut for

documentation and coding adjustments, a 0.4% decrease for a productivity adjustment, and a 0.2% reduction required by the Affordable Care Act.

CMS Proposes Rule to Update Payment Rates for Inpatient Rehab Facilities

CMS proposes to increase payments to inpatient rehab facilities (IRFs) in Fiscal Year 2015 by $160 million. The proposed rule also would revise and update quality measures and reporting requirements under the IRF Quality Reporting Program.

Proposed Rule for Payments to Inpatient Psychiatric Facilities

CMS proposed to increase payments to inpatient psychiatric facilities (IPFs) in Fiscal Year 2015 by 2.1%. The proposed rule also updates the IPF Quality Reporting Program, which requires participating facilities to report on quality measures or incur a reduction in their annual payment update.

New Payment System for Federally Qualified Health Centers

With the transition to a new payment system in Fiscal Year 2015, CMS has proposed to increase payments to federally qualified health centers (FQHCs) by 32%. The new payment system will pay FQHCs a single encounter rate per beneficiary per day for all services provided, with some exceptions. The same services that Medicare paid for in the past will continue to be covered.

With the transition to a new payment system in Fiscal Year 2015, CMS has proposed to increase payments to federally qualified health centers (FQHCs) by 32%

CMS Publishes Proposed Rule on Medicare Prospective Payment System for Fiscal Year 2015 for Skilled Nursing Facilities

CMS has issued the proposed rule on the Medicare Prospective Payment System for Fiscal Year 2015 for skilled nursing facilities (SNFs). The proposed market basket update is 2.0%. Further, CMS proposes to revise the Change of Therapy Other Medicare Required Assessment (COT OMRA) policy to permit SNFs to complete a COT OMRA for a resident who is not currently classified into a resource utilization group (RUG) therapy group, but only in rare cases where the resident has qualified for a RUG therapy group on a prior assessment during the current Medicare Part A stay and had no discontinuation of therapy services during a specified period.

STATE UPDATE

Orange MRI Owner Sentenced to 46 Months in Prison and Forfeits More Than $2 Million

The owner and medical director of Orange Community MRI LLC, a diagnostic imaging center in New Jersey, was sentenced to 46 months in prison and ordered to pay more than $2 million in connection with a scheme to pay physicians for their referrals of patients to the center. He also received three years of supervised release to follow the prison term. The owner negotiated, approved and paid kickbacks to physicians for each magnetic resonance imaging, ultrasound, echocardiogram, computed axial tomography and dual-emission X-ray absorptiometry they referred, and he provided cash to his subordinates to do the same. Seventeen other health care providers have been convicted in connection with the scheme as well.

Petition for Rulemaking on Scope of Practice of Dental Auxiliaries in an Orthodontic Office

The New Jersey Association of Orthodontists (NJAO) has petitioned the New Jersey Board of Dentistry to expand the functions of a limited registered dental assistant in orthodontics (LRDA-O) to include (1) holding and applying a curing light; (2) applying topical anesthetic; (3) applying topical fluoride; (4) placing and ligating archwires; and (5) preparing teeth for bonding. The NJAO also proposed to expand the functions of licensed dental hygienists, registered dental assistants and LRDA-Os to include (1) taking impressions for orthodontic appliances; (2) placing orthodontic separators; (3) removing bands and brackets without the use of rotary instruments; (4) removing primary adhesive after debanding/debonding without the use of rotary instruments; (5) performing intra-oral scanning for the purpose of obtaining digital study models or orthodontic appliances; and (6) under direct supervision, performing emergency treatment to provide immediate relief from an offending appliance.

HIPAA UPDATE

New York Health Organizations to Pay $4.8 Million HIPAA Fine

NewYork-Presbyterian Hospital will pay $3.3 million and Columbia University will pay $1.5 million to settle allegations that they failed to secure Protected Health Information (PHI) in accordance with the Health Insurance Portability and Accountability Act (HIPAA). The organizations disclosed to HHS' Office of Civil Rights that a breach under HIPAA occurred when a Columbia physician deactivated a personally owned computer server on the network containing NewYork-Presbyterian's electronic PHI (ePHI), which allowed the ePHI to become available on the Internet and accessible through search engines. Neither organization made efforts before the breach to ensure that the server was secure and contained appropriate software protections. In addition, neither NewYork-Presbyterian nor Columbia had conducted an accurate risk analysis that identified all systems that access the ePHI.

Stolen Computer HIPAA Penalties

Concentra Health Services and QCA Health Plan Inc. are each paying fines under HIPAA in matters involving stolen computers containing PHI. Concentra is paying $1.7 million and QCA is paying $250,000. In both instances, the computers were unencrypted.