Medicare's Time Limit for DGME and IME Claims Associated With Part C Services is Rejected by the D.C. Circuit

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On December 2, the Court of Appeals for the District of Columbia Circuit affirmed the ruling in Loma Linda v. Sebelius, 684 F.Supp. 2d 42 (D.D.C. 2010) that it was arbitrary and capricious for the Secretary to conclude that a hospital filing claims with its Part A fiscal intermediary for medical education expenses associated with Medicare Part C services should have inferred that the Medicare Fee-For-Service regulatory time limits applied. This means that hospitals with unbilled or rejected claims for medical education costs associated with Part C services should consider billing these claims and exercising their appeal rights to recover what could be substantial payments owed to them.

In the Balanced Budget Act of 1997 (BBA 97) Congress required Medicare to pay Direct Graduate Medical Education (DGME) costs and Indirect Medical Education (IME) costs directly to the teaching hospitals providing the services. These payments were in addition to the payments hospitals received from Medicare Managed Care Plans under either negotiated contract rates or 42 C.F.R. 422.214 for non-contracted plans. This represented a significant increase in revenue for teaching hospitals as DGME and IME had previously been paid by capitation directly to Medicare plans.

CMS directed hospitals to claim these DGME and IME payments by submitting bills to their Medicare Part A fiscal intermediaries. For a variety of reasons, many hospitals initially had problems in obtaining payment under this process for substantial number of Medicare managed care beneficiaries. One reason that continues to affect teaching hospital's ability to bill all claims is the requirement that the Medicare Health Insurance Card (HIC) number must be on the bill for the system to accept it. The Medicare managed care patient will present her plan card with its unique identifying number, but may balk at supplying her HIC number as she is no longer covered by traditional Medicare.

Several hospitals were refused substantial amounts of DGME and IME by the fiscal intermediary on the basis that they had missed the deadline in the Secretary's billing regulations at Part 425 of the Code of Federal Regulations. These hospitals argued that 42 C.F.R. § 424.30 excepts from the Part 425 regulations "all cases . . . when services are furnished on a prepaid capitation basis." Medicare managed care plans continued to be paid by capitation after BBA 97. Hospitals argued that the Part A billing time limit did not apply to a claim for DGME and IME associated with associated with Part C services. Several hospitals appealed to the Provider Reimbursement Review Board and won. The CMS Administrator overruled all of these cases stating that he "interpreted" the exclusion in 42 C.F.R. § 424.30 to not include claims for medical education costs associated with Part C services because these were "Part A services."

In February of this year, the District Court for the District of Columbia in Loma Linda v. Sebelius, 684 F.Supp. 2d 42 (D.C. 2010) held that the CMS Administrator's conclusion that teaching hospitals should have inferred that the regulation governing the application of Part A claims applied to medical education claims associated with Part C services was arbitrary and capricious under the Administrative Procedure Act. This "rule" was thus invalid.

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CDPH Set to Launch Rulemaking on Administrative Penalties for Medical Information Breaches and Immediate Jeopardy and Adverse Events

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In recent years, the California legislature has passed laws that allow discretionary administrative penalties against health facilities of up to $100,000 per violation for medical information breaches, "immediate jeopardy" situations, and adverse (the so-called "never") events. The State has assessed such penalties against many providers despite not yet having promulgated regulations to implement these new laws. The California Department of Public Health (CDPH) is now preparing to promulgate regulations. It is holding public meetings and inviting written comments on December 14 (medical information breaches) and January 10 (immediate jeopardy and adverse events) to give interested persons the opportunity to shape how these laws will be applied in the future. Formal rulemaking will follow, which will provide another opportunity for public comment.

Background

In 2008, the California legislature adopted SB 541 (Alquist), which increased the administrative penalties the CDPH may assess against hospitals for deficiencies that present "immediate jeopardy" to the health or safety of patients. The bill also authorized the CDPH to levy administrative penalties against facilities for failure to prevent unlawful or unauthorized access, use, or disclosure of patient medical information, and for failure to report instances of unlawful or unauthorized access, use, or disclosure of information.

SB 541 followed 2006 legislation, SB 1301(Alquist), which required hospitals to report 27 enumerated adverse events, the so-called "never" events, as well as a 28th general event defined as "an adverse event or series of events that cause the death or serious disability of a patient, personnel, or visitor," to the CDPH no later than 5 days after the detection of the adverse event (or 24 hours in the case of an urgent or emergent threat).

Administrative Penalties for Medical Information Breaches

The statute governing medical information breaches, Health & Safety Code section 1280.15, authorizes the CDPH to assess, after investigation, an administrative penalty for unlawful or unauthorized access or use of medical information of up to $25,000 per patient, and up to $17,500 per subsequent occurrence involving the same patient's medical information. Section 1280.15 provides that the CDPH shall consider the provider's history of compliance with section 1280.15 and other related state and federal statutes and regulations, the extent to which the facility detected violations and took preventative action to immediately correct and prevent past violations from recurring, and factors outside the facility's control that restricted the facility's ability to comply with section 1280.15. The statute also states, "The department shall have full discretion to consider all factors when determining the amount of an administrative penalty pursuant to this section."

Although the CDPH has yet to promulgate regulations to implement this section, according to its website, it assessed penalties against 14 hospitals for violations of this section in 2010, raising

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The Secretary appealed this ruling to the United States Court of Appeals for the District of Columbia Circuit. On December 2, the D.C. Circuit affirmed the District Court's ruling on the basis that Loma Linda did not receive notice "with ascertainable certainty" of the Administrator's new interpretation that the exclusion at 42 C.F.R. § 424.30 now included claims for medical education costs associated with Part C services that were paid on the basis of capitation to Medicare plans. Loma Linda v. Sebelius, 2010 WL 4903887 (D.C. Cir. 2010).

CMS is currently considering its response to this ruling. The CMS Administrator's Decisions in the several appealed cases which "interpreted" 42 C.F.R. § 424.30 to include claims for medical education costs associated with Part C services arguably give notice to providers. However this notice did not occur until varying dates in 2008, and would also be invalid if applied before these Decisions were published. Moreover, there are legal issues as to whether a non-precedential provider specific CMS Administrator's Decision is an adequate means to give notice to all providers.

If Medicare persists in applying its interpretation of the existing 42 C.F.R. § 424.30, several additional arguments that were not reached in Loma Linda could reasonably defeat this rule on alternate legal administrative law principles such as that the new rule 1) is inconsistent with the text of the regulation, 2) is invalid because the regulation was not amended under notice and comment rulemaking, 3) cannot fairly be seen as an "interpretation" and was made without notice and comment rulemaking, or 4) is prohibited under the Paperwork Reduction Act as a duplicate filing requirement.

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questions as to how it is exercising its "full discretion" in the absence of regulations or whether it is indeed exercising the discretion given to it by statute.

The pre-notice meeting regarding regulations governing medical information breaches was held on Tuesday, December 14, 2010. Formal rulemaking will follow, which will provide interested parties with opportunity to comment on proposed regulations drafted by the CDPH.

Administrative Penalties for Immediate Jeopardy and Adverse Events

Under Health & Safety Code sections 1280.1 and 1280.3, a facility can be assessed an administrative penalty in an amount not to exceed $100,000 per violation if it receives a notice of deficiency constituting an immediate jeopardy to the health or safety of a patient. "Immediate jeopardy" is defined as a situation in which the licensee's noncompliance with one or more requirements of licensure has caused, or is likely to cause, serious injury or death to the patient. The statute gives the CDPH "full discretion" to consider all factors when determining the amount of an administrative penalty pursuant to these sections.

The CDPH is also directed to promulgate regulations establishing criteria to assess an administrative penalty, which shall include, but is not necessarily limited to, (1) the patient's physical and mental condition, (2) the probability and severity of the risk that the violation presents to the patient, (3) the actual financial harm to the patients, if any, (4) the nature, scope, and severity of the violation, (5) the facility's history of compliance with related state and federal statutes and regulations, (6) factors beyond the facility's control that restrict the facility's ability to comply with the statute, (7) the demonstrated willfulness of the violation, and (8) the extent to which the facility detected the violation and took steps to immediately correct the violation and prevent the violation from recurring.

Health & Safety Code sections 1279.1 and 1280.4 address a health facility's obligation to report an adverse event to the CDPH. A facility is required to report an adverse event within 5 days after the event has been detected (or 24 hours if the event is an ongoing urgent or emergent threat to the welfare, health or safety of patients, personnel, or visitors). A failure to report an adverse event may result in a civil penalty in an amount not to exceed $100 for each that that the adverse event is not reported following the initial 5-day or 24-hour period. While these statutes do not expressly address the CDPH's discretion, it would appear the types of factors identified in the immediate jeopardy statute should also be taken into consideration in addressing civil penalties in an adverse event situation.

A pre-notice meeting regarding regulations governing these administrative penalty regulations will be held on Monday, January 10, 2011, at the East End Complex Auditorium, 1500 Capitol Avenue, Sacramento, California 95814 at 8:30 a.m. Any interested person may present oral or written comments at the meeting, or can submit written comments to the Contact Person identified in the CDPH Notice not later than 5:00 p.m. on Monday, January 10, 2010. A copy of the Notice can be found on the CDPH website at http://www.cdph.ca.gov/programs/LnC/Pages/AP-Pre-Notice-Meeting.aspx.