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New Rules Prohibiting the Government's Use of Certain 'Guidance Documents' May Reduce False Claims Liability for Health Care Providers

Health care providers and others in the health sector have long complained at the unfairness of facing enforcement actions – and the fines and penalties that accompany them – for failure to follow a poorly publicized or otherwise obscure agency guidance such as a local coverage determination (LCD). In 2019, the United States Supreme Court provided significant relief when it held in *Azar v. Allina Health Services*, 139 S. Ct. 1804 (2019), that an agency guidance that established or changed a "substantive legal standard" had to undergo a notice-and-comment process before adoption and enforcement. On Dec. 3, 2020, the Office of General Counsel for the Department of Health and Human Services (HHS-OGC) issued an Advisory Opinion and two final rules that provide a roadmap as to how the agency plans to implement the *Allina* decision, including how such guidance documents may be employed in civil enforcement proceedings such as False Claims Act cases. Because they impact both pending and future enforcement actions, these newly issued authorities represent a significant development in the area of health care enforcement.

The *Allina* Decision

As noted, the Dec. 3 Advisory Opinion and accompanying regulations represent the agency's response to the United States Supreme Court's decision in *Azar v. Allina Health Services*, 139 S. Ct. 1804 (2019). That case invalidated the use of guidance posted by the Centers for Medicare and Medicaid's (CMS) relating to

disproportionate share payment to hospitals. The Court held that the guidance, which was published only on the internet, failed to comply with the notice-and-comment requirement expressly set forth in § 1871 of the Social Security Act (SSA), which requires that the government provide the public with advance notice and a chance to comment on any rule, requirement, or other statement of policy that establishes or changes a "substantive legal standard" governing the payment for services. The Court held that CMS's disproportionate share payment guidance established or changed a "substantive legal standard," and hence required that the notice-and-comment requirement be satisfied before proper issuance. In ruling that this guidance was invalid and unenforceable, the Court declined to define the parameters of what qualified as a "substantive legal standard" under the SSA, but held that the standard for notice and comment was more stringent under the SSA than the general standard applicable to most agencies under the Administrative Procedure Act (APA).

New Advisory Opinion

In its Dec. 3 Advisory Opinion, HHS's Office of General Counsel set out its interpretation of the SSA's phrase "substantive legal standard": any issuance that defines, in part or in whole, or otherwise announces binding parameters governing, any legal right or obligation relating to the scope of Medicare benefits, payment by Medicare for services, or eligibility of individuals, entities, or organizations to furnish or receive Medicare services or benefits, and sets forth a requirement not otherwise mandated by statute or regulation. The definition of these interpretive parameters is a significant development for individuals and entities operating under the strictures of federal health care regulation insofar as they impose a strict requirement on when and how HHS-OGC can issue binding requirements on regulated entities and individuals. In addition to acknowledging the Court's *Allina Health Services* holding (as it must), this Advisory Opinion provides clarity on when HHS (and CMS) will be issuing notices for comments before imposing additional, new, or revised requirements in connection with Medicare reimbursed goods or services.

The Advisory Opinion also sets out HHS-OGC's position as to current and future use and enforceability of the Medicare Internet-Only Manuals (IOM) available on the CMS website. HHS-OGC sets out that, where the IOMs and other CMS-issued guidance (including preambles and text published with proposed or final rules) are closely tied to existing statutory or regulatory requirements, enforcement actions based upon violations of the IOM guidance materials remain viable because these sub-regulatory guidance documents are, in these circumstances, not establishing or changing a substantive legal standard, but rather "aid[ing] in demonstrating that the standards in the relevant statutory and regulatory requirements have been or have not been satisfied." In other words, HHS-OGC is taking the position that the Department can issue (and has issued in the IOM) ***interpretations*** of existing laws and regulations without providing notice and an opportunity for comment. The difference between an interpretation of an existing law or regulation versus a change to a substantive legal standard is often, of course, the proverbial ballgame.

Notwithstanding the Advisory Opinion, after *Allina*, violation of standards or rules set out in Medicare guidance documents that are not closely tied to already enacted statutory or regulatory standards cannot be used as a basis for a government action. The critical question is whether the violation of the Medicare rule could be established absent the guidance document. If not, then the guidance document is invalid unless issued through notice-and-comment rulemaking.

With regard to LCDs, which often form the bases of claim denials, the Advisory Opinion sets out HHS-OCG's position that because LCDs are not binding on HHS, they do not establish or change substantive standards. Nevertheless, the Advisory Opinion provides that enforcement actions based on LCDs are not supportable.

Finally, the Advisory Opinion addresses the appropriate use of preamble text and concludes that, while preambles often contain interpretive statements, they are not binding rules and as such do not, by themselves, need to satisfy SSA notice-and-comment requirements before issuance. When HHS engages in notice-and-comment rulemaking through preamble language only, it must be sufficiently clear to separate binding legal obligations from the rest of the preamble text that contains nonbinding interpretive statements. To do so, it must say "HHS intends to bind itself" to the rule or state that HHS will engage in notice-and-comment rulemaking to change the stated preamble policy.

New Federal Regulations

After issuance of the Advisory Opinion, HHS issued formal rules (published Jan. 12, 2021) codifying the proper use of guidance documents. These new regulations prohibit the government's use of guidance documents to impose binding requirements or prohibitions on outside parties unless specifically authorized by law or contained in a contractual provision in a governmental contract; and further provide that the government may not treat noncompliance with a standard or practice announced solely in a guidance document itself as a violation of applicable statutes or regulations except as expressly authorized by law. HHS may only rely on and cite guidance documents that are compliant with the document publication requirements of the new regulations.

The new regulations differentiate between a general "guidance document," which is a statement of general applicability, intended to have future effect on the behavior of regulated parties that sets forth a policy on statutory, regulatory, or technical or scientific issues or an interpretation of a statute or regulation; and a "significant guidance document," which is one that may reasonably be anticipated to lead to an annual impact on the economy of $100 million or more or otherwise adversely affect the economy of a sector of the economy. The regulations prohibit HHS from issuing any guidance document that establishes a legal obligation not reflected in any statute or regulation and may not issue a guidance document for purposes of requiring a person to take, or refrain from taking, any action beyond that required by existing statute or regulation.

Further, each guidance document must: (1) identify itself as "Guidance" and include specific statements that the document does not have the effect of law and is merely to clarify an existing requirement; (2) not direct parties to take any action or fail to act unless based upon statute, regulation, or judicial precedent and (3) provide specific information such as the activities to which the guidance applies, date, agency, a statement of whether it reverses or replaces other guidance, citation to statutes or regulations, and a summary of the guidance document. The secretary of HHS must approve each such guidance document before its issuance.

Before issuance, "Significant guidances," as defined in the new regulations, must be submitted to HHS's Office of Information and Regulatory Affairs for review and provided to the public with a notice and comment period of at least 30 days. This public notice must include practical information on where to find the proposed guidance and how to submit comments relating thereto.

The new regulations also require that HHS maintain a guidance repository that is fully searchable. Failure to include a guidance document in the repository within 30 days of publication automatically rescinds it. Any webpage in the guidance repository must contain statements that the guidance lacks force and effect of law and may not be cited or relied upon by HHS unless it is posted in the repository. Any existing guidance that is not placed in the repository is deemed rescinded.

Finally, the new regulations effectively create an opportunity to appeal beyond the initial notice-and-comment period. They provide that any party may petition HHS to withdraw or modify a guidance

document if it imposes binding obligations beyond those required by statute or regulation, creates additional legal obligations, or is improperly exempted from the requirements of the regulations. Requests to modify or withdraw such documents must be made in writing, and HHS has 90 days to respond unless it requests additional information or notifies the requestor that it needs to consult with other agencies prior to responding. Responses must be posted to the repository website.

Significance

These new regulations apply far beyond the parameters of the Medicare program and apply to all components of HHS, including the Food and Drug Administration until such time as the FDA revises its regulations. In addition, together with the Advisory Opinion, the new regulations will necessarily impact existing and future cases brought under the False Claims Act, 31 U.S.C. §§ 3729 *et seq*, which expose defendants to having to pay steep fines, not to mention treble damages.

Prior to *Allina*, False Claims Act complaints were often premised on billing issues discovered during reviews or audits involving claims that the government later contended were improper because they failed to comply with some form of regulatory guidance. *See, e.g., Unites States ex rel. Godecke v. Kinetic Concepts, Inc.*, 2016 U..S. Dist. LEXIS 200426 (C.D. Ca.) (claims did not comply with Medicare Manual and Local Coverage Determination); *United States v. Sklar*, 273 F. Supp. 3d 889 (N.D. Ill. 2017) (utilizing LCDs to determine false claim). *Compare United States ex rel. Montcrieff v. Peripheral Vascular Assocs, P.A.,* 2020 U.S. Dist LEXIS 233911 (utilizing failure to comply with CPT guidance as basis for false claim). LCDs in particular were often cited as the basis for the legal violation, notwithstanding that the defendant-provider had no actual knowledge of the given LCD or easy way to discover it.

Because the HHS-OGC Advisory Opinion and regulations define when the agency must provide notice and an opportunity to comment on proposed guidances before they are issued, and how it must publicize them once the guidances are adopted, the days of the agency playing "gotcha" should effectively be gone. Not only will the agency be prohibited from effectively issuing stealth billing rules, it is prohibited (by *Allina*) from attempting to enforce those it issued previously absent the full notice-and-comment process. The inability to use past sub-regulatory guidance for enforcement purposes provides a potential defense to some forms of False Claims Act liability and may narrow the circumstances under which law enforcement authorities can prove a False Claims Act violation.

It remains to be seen whether the current administration will alter the Opinion or regulations although, given that they implement the Supreme Court's ruling, any changes are likely to be comparatively minor.

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