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# The Time Is Now For A Blanket Stark Law Waiver

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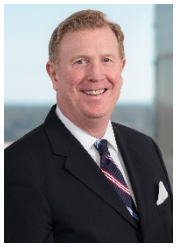
Published in Law360 | March 23, 2020


Section 1135 of the Social Security Act grants broad administrative authority to the secretary of the U.S. Department of Health and Human Services to waive or modify various programmatic requirements of the federally funded health care programs overseen by HHS. Such authority is triggered by the president's declaration of a disaster or emergency under the Stafford Act or National Emergencies Act, coupled with a declaration of a public health emergency under the Public Health Service Act by the secretary.

The basic purpose of an 1135 waiver is to assure sufficient health care items or services are available to meet the needs of program beneficiaries affected by the emergency or disaster and assure that providers acting in good faith get paid and, absent determinations of fraud or abuse, are exempted from otherwise applicable sanctions.

HHS Secretary Alex Azar declared a public health emergency regarding the coronavirus on Jan. 31.

In response to President Donald Trump's emergency declaration on March 13, Secretary Azar issued that same day a Section 1135 waiver under Titles XVIII (Medicare), XIX (Medicaid) and XXI (State Children's Health Insurance Program) of the Social Security Act and regulations promulgated thereunder, but "only to the extent necessary, as determined by the Centers for Medicare & Medicaid Services, to ensure that sufficient health care items and services are available to meet the needs of [individual beneficiaries] … and to ensure that health care providers that furnish such items and services in good faith, but are unable to comply with one or more of these requirements as a result of the 2019 Novel Coronavirus COVID-19 pandemic, may be reimbursed for such items and services and exempted from sanctions for noncompliance, absent any determination of fraud or abuse."

Among other programmatic requirements, the 1135 waiver pertains to:

- Certain conditions of participation, certification requirements, program participation or similar requirements applicable to individual and entity health care providers (i.e., physicians, hospitals, etc.)
- Requirements that health care professionals be licensed in the state where they provide services, provided they have an equivalent license from another state and are not otherwise debarred from practice under that license

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- Sanctions under Section 1867 (the Emergency Medical Treatment and Active Labor Act), which bars so-called "patient dumping" if the transfer at issue is pursuant to a state emergency preparedness plan or if the transfer of an unstabilized individual is necessitated by circumstances of the COVID-19 emergency

- Sanctions under Section 1877(g) (the Stark Law), which includes certain limitations on physician referral, under such conditions and in such circumstances as CMS determines appropriate

- Payment limitations under Medicare Advantage plans for items and services furnished by out-of-network professionals or facilities

- Sanctions and penalties under specific provisions of the Health Insurance Portability and Accountability Act privacy regulations to remove (1) the requirement of obtaining a patient's agreement to speak with friends or family members or to honor a patient's request to opt out of the facility's patient directory, (2) the requirement to distribute a notice of the facility's privacy practices and (3) the patient's right to request privacy restrictions or confidential communications — but only with respect to hospitals operating under disaster protocols while the waiver is in effect and only for a 72-hour period from the implementation of the disaster protocol.

The waivers were given retroactive effect to March 1 and are to continue during the period the national emergency is in effect.

While these waivers hold the promise of a potential lessening of complex and burdensome restrictions that providers must otherwise navigate under normal circumstances, they appear to be contingent in practical effect. The contingent nature arises from the fact that they are subject to the further determination of necessity by the Centers for Medicare and Medicaid Services.

Thus, while Secretary Azar's prompt action in issuing the 1135 waiver provides a measure of comfort to a provider confronting an emergency of unprecedented scope and unknown duration, that waiver does not provide concrete actionable guidance in terms of just how much leeway to stray from otherwise applicable regulatory requirements the provider community has been given.

To be sure, CMS has acted with dispatch in building out the scope of the 1135 waiver by issuing certain "blanket waivers."[1]

However, CMS has yet to issue its determination of what conditions and circumstances are appropriate with respect to the waiver or modification of sanctions otherwise applicable to financial relationships between referring physicians and entities providing designated health services under the Stark Law.

Moreover, because physician financial relationships with entities to which they may refer government program patients may also implicate the provisions of the federal Anti-Kickback Statute, any waiver of Stark Law sanctions may end up being "half a loaf" and leave providers who act in good faith in modifying physician compensation arrangements in response to the COVID-19 emergency exposed to claims by plaintiff whistleblowers of violating the Anti-Kickback Statute and thereby engaging in deemed violations of the federal False Claims Act.

This is an untenable position for providers coping with the COVID-19 crisis.

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The need for prompt administrative action here is real, not theoretical. Many health care delivery systems that employ physicians either directly through hospitals or through controlled affiliates to comply with state corporate practice of medicine restrictions rely upon productivity-based compensation plans to provide appropriate incentives to their physician workforce. But the manner in which such plans operate may be upended by substantial reductions in caseload handled by employed physicians, particularly proceduralists.

Left unchecked, those reductions in caseload could result in substantial reductions in physician compensation, an outcome certainly at odds with providing reassurance and financial stability to professionals manning the front lines in the pandemic. The adverse financial impact on physicians in independent practice on whom many hospitals rely as a collaborative workforce organized as a medical staff could be even greater because their livelihoods are tied more directly to the volume of patient care services they deliver without the economic resources of a large multihospital system.

But providing financial resources to referring physicians in the face of COVID-19's disruptive impact to assure the continued availability of physicians presents considerable risk of what the health care bar often labels "technical violations" of Stark. For example, a financial arrangement as simple as a hospital's good faith agreement to provide an income guarantee mechanism for a physician to backstop a shortfall in earned compensation occasioned by COVID-19's disruptive impact presents potentially significant compliance risks under Stark. That regulatory obstacle should be eliminated, promptly.

The stakes of the COVID-19 emergency are no doubt high, but with multimillion-dollar claims being advanced against providers for technical "foot faults" occurring under the Stark Law, the risks to providers are not inconsequential. Navigating Stark's byzantine requirements is a task undertaken with confidence only by providers who engage competent counsel with substantial experience in this highly specialized area. At least one federal appeals judge has characterized the law as an "impenetrably complex set of laws and regulations."[2]

Even before COVID-19 turned our health care world upside down, CMS was proposing substantial curtailments of the application of the Stark Law (and the HHS Office of Inspector General was proposing companion safe harbors under the Anti-Kickback Statute) to facilitate the development of value-based compensation arrangements in the efforts to migrate the delivery system away from one which concentrates incentives on the volume of care rather than value. That rulemaking is an implicit recognition of the fundamental obstacles that the Stark Law (and to an extent, the Anti-Kickback Statute) erect in efforts to transform our health care delivery system.

In the face of the current COVID-19 pandemic, those obstacles serve no meaningful public purpose and inhibit the resourcefulness of the provider community in making the highest and best use of available resources.

Accordingly, for any waiver of the Stark Law limitations to be useful, it must be capable of being applied without the need for the bevy of attorneys, compensation consultants and valuation experts that usually attend the development and implementation of a health care system's physician compensation plan.

In short, the Stark Law waiver that is needed here and now is a blanket suspension of the application of the Stark Law and regulations to any compensation that a physician receives from a facility providing designated health services for a period of time commencing on March 1 and ending upon a date certain

to be specified upon the cessation of the COVID-19 emergency.

The contours of such a waiver could be simply stated as follows:

1. Remuneration does not include any compensation paid by a designated health services entity to a physician for the provision of professional services to patients during the waiver period, provided such compensation does not ratably exceed the 90th percentile of specialty specific annual compensation as reported by a national survey body's most recent national survey published prior to March 1, 2020.

2. Remuneration does not include any compensation paid by a designated health services entity to a physician employed by such entity (or a commonly controlled affiliate thereof) where such compensation is paid for the purpose of maintaining the historic rate of compensation earned by the physician notwithstanding any reduction in physician productivity that may be occasioned by the COVID-19 emergency.

Anything short of a simple blanket waiver leaves providers unfairly exposed and will fail the essential purpose of the 1135 waiver authority — to assure the availability of services to program beneficiaries.

**Notes**

1. See COVID-19 Emergency Declaration Health Care Providers Fact Sheet

2. United States ex rel. Drakeford v. Tuomey, 792 F.3d 364, 390 (4th Cir. 2015 (Wynn, concurring) )

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