

Significant Changes in Healthcare Laws Enacted Through the Bipartisan Budget Act of 2018: Stark, Civil and Criminal Penalties, Telehealth, ACOs and More

February 21, 2018 – Dorsey Health Law

by Ross C. D'Emanuele, Benjamin Fee, and Laura B. Morgan

Overview

On February 9, President Trump signed the Bipartisan Budget Act of 2018 (“BBA”) into law. The BBA funds the federal government through March 23 and included a bipartisan agreement to increase annual spending authority for a two-year period. In addition, the legislation contains significant policy changes

impacting Medicare, Medicaid and other federal health agencies.

These changes include revisions to the federal physician self-referral law (commonly referred to as the “Stark Law”), expansion of coverage for telehealth services, funding extensions of several critical Medicare programs, and changes to the Medicare Shared Savings Program. A summary of some of these key health care policy changes is included below.



Related People

- Ross C. D'Emanuele

Related Capabilities

- Healthcare & Life Sciences
- Healthcare Transactions & Regulations
- Healthcare Litigation
- Medical Devices

Revisions to the Stark Law

The BBA revised the Stark Law to codify certain regulatory changes that went into effect on January 1, 2016 and corresponding clarifications via preamble by the Centers for Medicare & Medicaid Services (“CMS”) in the 2016 Medicare Physician Fee Schedule Final Rule (the “2016 Final Rule”). Specifically, the BBA revised the Stark Law to indicate the following:

1. The writing requirement of various Stark Law compensation exceptions can be

satisfied “. . . by a collection of documents, including contemporaneous documents evidencing the course of conduct between the parties involved.” Previously, CMS had only indicated in preamble text in the 2016 Final Rule that a collection of documents could be relied upon to meet the writing requirement. This was not set forth in regulatory text, however. Now that this language is in the Stark Law itself, stakeholders can take greater comfort in relying on a collection of documents to meet the writing requirement.

2. The signature requirement of various Stark compensation exceptions is met if the parties obtain the required signatures “not later than 90 consecutive calendar days immediately following the date on which the compensation arrangement became noncompliant” and the arrangement otherwise complies with all applicable criteria. This statutory language now aligns with regulatory language in 42 C.F.R. § 411.353(g) regarding temporary noncompliance with signature requirements. That regulatory language was revised in the 2016 Final Rule to provide organizations with greater flexibility and to eliminate the prior rule that included a confusing, and often unhelpful, distinction between inadvertent noncompliance *not* inadvertent noncompliance. The Stark Law itself, however, has not previously referenced any provisions with respect to temporary noncompliance with the signature requirements.
3. A holdover lease or personal service arrangement can indefinitely meet the requirements of the Stark exceptions for rental of office space, rental of equipment and personal service arrangements, respectively. However, the immediately preceding arrangement must have expired after a term of at least one year, the arrangement must have met all requirements of the applicable exception when it expired, the holdover arrangement must be on the same terms and conditions as the immediately preceding arrangement, and the holdover arrangement must continue to satisfy the conditions of the applicable exception. This statutory language now aligns with regulatory language regarding holdovers in the rental of office space, rental of equipment and personal service arrangements exceptions in 42 C.F.R. § 411.357. That regulatory language was revised in the 2016 Final Rule which previously only permitted holdovers for up to six months. The Stark Law itself, however, has not previously referenced any provisions with respect to holdover arrangements.



These Stark-related provisions of the BBA used the language from Section 301 of [H.R.3178](#), titled the “Medicare Part B Improvement Act of 2017,” which we summarized in our blog post [here](#). This bill, which includes many other non-Stark Law-related provisions, is still pending in the Senate.

We note that, while the changes to the Stark Law under the BBA were fairly inconsequential, broader Stark Law reform initiatives, including in response to the move to value-based payments under Medicare, are also currently underway. See our blog post [here](#) for further details.

Increase in Civil and Criminal Penalties for Violations of Fraud and Abuse Laws

The BBA significantly increased civil and criminal penalties for federal health care program fraud and abuse. Specifically, existing maximum penalties under the Civil

Monetary Penalties Law (“CMPL”) for improperly filed claims (under 42 U.S.C. § 1320a–7a(a)) increased to \$20,000 (from \$10,000), to \$30,000 (from \$15,000), and to \$100,000 (from \$50,000). Maximum penalties under the CMPL for payments to induce reduction or limitation of services (under 42 U.S.C. § 1320a–7a(b)) increased to \$5,000 where they were previously \$2,000 and \$10,000 where they were previously \$5,000.

Additionally, criminal penalties for acts involving federal health care programs under 42 U.S.C. § 1320a–7b, including but not limited to the Anti-Kickback Statute, were increased to \$100,000 (from \$25,000), to \$20,000 (from \$10,000), and to \$4,000 (from \$2,000). Finally, maximum sentences for felonies involving federal health care program fraud and abuse under 42 U.S.C. § 1320a–7b, including but not limited to the Anti-Kickback Statute, were increased to ten years where they were previously five years. The effective date of these increased penalties is February 9, 2018 (the date of enactment of the BBA).

We note that, in 2016, penalties under the CMPL and for criminal acts involving federal health care programs were adjusted for inflation in accordance with the Bipartisan Budget Act of 2015 (see 81 Fed. Reg. 61538 et seq. (Sept. 6, 2016)), and are adjusted on an annual basis under 45 C.F.R. § 102.3 (but have not yet been updated for 2018). So, the previous statutory maximum penalties had already been increased from the amounts set forth in the statute, and now have been increased even further. It is not clear how inflation adjustments will be applied in 2018 to the new statutory penalty maximums under these laws.

Medicare Telehealth Expansion

The BBA also included potentially far-reaching expansions to Medicare coverage for telehealth services.

Telehealth Services for Stroke Patients

Current Medicare coverage for telehealth services is limited to certain care locations that are either: (A) outside of any Metropolitan Statistical Area and designated as a rural health professional shortage area; or (B) participating in a Federal telemedicine demonstration project.

The BBA eliminates this originating site requirement beginning January 1, 2019 for services to diagnose, treat, or evaluate symptoms of an acute stroke. The Medicare beneficiary receiving diagnosis, treatment, or evaluation of an acute stroke may be located at any hospital or critical access hospital, mobile stroke unit, or any other type of care site that CMS designates.

Home Dialysis Assessments

Similarly, beginning January 1, 2019 Medicare beneficiaries with End Stage Renal Disease (“ESRD”) may choose to receive monthly ESRD-related clinical assessments via telehealth. A face-to-face clinical assessment will be required monthly during the

initial 3 months of home dialysis, and thereafter only once every 3 consecutive months.

The statute also states that the provision of telehealth technologies to a Medicare beneficiary receiving home dialysis will not be considered remuneration under the beneficiary inducement statute, so long as the telehealth technologies are not offered as part of any advertisement or solicitation, are provided for purposes of furnishing telehealth services related to the beneficiary's ESRD, and meet any other requirements CMS may adopt by regulation.

The condition-based expansions in telehealth coverage for ESRD and stroke patients beyond rural health professional shortage areas signals an important recognition that service delivery via telehealth is both effective and increasingly common.

Telehealth Services Provided Under Medicare Advantage Plans

Beginning in plan year 2020, a Medicare Advantage Plan ("MA Plan") may provide additional telehealth benefits to its enrollees. The telehealth benefits must be a service type available under Medicare Part B, and must be services that the MA Plan identifies as clinically appropriate to furnish using electronic information and telecommunications technology when a clinician is not at the same locations as the plan enrollee. CMS will adopt regulations regarding physician and practitioner requirements, coordination of benefits rules, and other requirements.

If the MA Plan wishes to offer the service via telehealth, the MA Plan must offer the same benefit in-person and allow the enrollee to determine whether or not to receive the benefit via telehealth.

The MA Plan's bid to CMS must attribute the telehealth benefit cost to amounts attributable to the provision of benefits under the original Medicare fee-for-service program.

Telehealth Services to ACO Beneficiaries

Lastly, the BBA allows increased Medicare coverage for telehealth services provided to Medicare fee-for-service beneficiaries assigned to an Accountable Care Organization ("ACO") participating in certain Medicare shared savings programs.



After January 1, 2020, the existing Medicare telehealth geographic limitations will not apply when a physician or practitioner participating in an ACO provides telehealth services covered under Medicare to a Medicare beneficiary assigned to the ACO. The beneficiary's home can be an originating site for the telehealth services, but the

beneficiary's home need not be located in a rural health professional shortage area.

This expansion in telehealth coverage applies only to ACOs participating in a two-sided ACO model (in which the ACO shares in both savings and losses), or an ACO tested and expanded pursuant to authority granted to the Center for Medicare and Medicaid Innovation.

No facility fee will be paid; only the professional service is paid pursuant to this telehealth expansion. And coverage does not extend to services appropriate only for hospital inpatients.

Other ACO Changes

The BBA includes a provision allowing ACOs to elect to have beneficiaries assigned to the ACO prospectively rather than having Medicare beneficiaries attributed to ACOs retroactively using encounter data based upon visits for primary care services. A beneficiary may also choose to align with an ACO in which his or her main primary care provider participates. The beneficiary can continue to receive services from any provider participating in Medicare even if he or she elects to align with a specific ACO.

The BBA also establishes a new voluntary ACO beneficiary incentive program that allows certain two-sided risk ACOs to offer beneficiaries a payment of up to \$20 per service for receiving select primary care services. ACOs that want to offer payment to beneficiaries will have to apply for approval to participate in the incentive program with Health and Human Services.

Outpatient Therapy Payments

The BBA repeals annual payment caps for outpatient hospital therapy services (including physical therapy, speech-language pathology services, and occupational therapy) effective January 1, 2018.

Funding Extensions

The BBA includes a number of funding extensions for critical health care programs, including:

- Extension of CHIP funding for four more years (Fiscal Year 2024 through Fiscal Year 2027);
- Five-year extension of the Medicare low-volume hospital payments through September 30, 2022;
- Five-year extension of the Medicare-dependent hospital (MDH) program through September 30, 2022.
- Two-year extension of funding for quality measure endorsement, input, selection, and reporting requirements.
- Five-year extension with reforms of the home health rural add-on until October 1, 2022.