



Policy Brief

July 27, 2018



Proposed Overhaul of Evaluation and Management (E/M) Codes

CMS is proposing to streamline the E/M codes for office and outpatient visits in its [CY 2019 Physician Fee Schedule](#) rule. If finalized, there will only be a single documentation requirement and payment rate for E/M levels two through five. CMS predicts that this policy will save 51 hours of medical documentation per clinician annually and eliminate [500 years of administrative burden](#). Despite the reduced burden, [physicians fear](#) the policy could lead to significant payment cuts for certain specialties. Although these changes would only apply to office and outpatient visits (codes 99201-99215), the agency intends to streamline other E/M code categories in the future. Below is more information on this proposal and its implications. For a full outline of the proposed rule, click [here](#).

Under the E/M proposal, physicians that tend to have higher intensity office visits will face higher risk of underpayment. For example, oncologists could receive a 7% payment cut and rheumatologists an 8% cut. To mitigate this, CMS proposes creating new add-on codes for certain specialties and a prolonged services code for care lasting 30 minutes beyond the typical time. Verma estimates that most providers will only see increases or decreases of 1-2%, after adjusting for the add-on codes. CMS proposes to adopt these changes on January 1, 2019 but seeks comments on whether to delay implementation for a year until January 1, 2020.

Please contact us if you have any interest on providing feedback on the proposed rule.



The State of the Health Insurance Exchanges

So far, 2018 has been a rough year for the Affordable Care Act's (ACA) Health Insurance Exchanges. News of the individual mandate repeal, legalization of [alternative insurance markets](#) and [suspension](#) (and confusingly abrupt [restoration](#)) of the risk adjustment payments has injected fresh uncertainties into the market. Insurers' trepidation is growing, which may translate to higher premiums, an increased uninsured or underinsured population and greater hospital bad debt. Here's a snapshot of the current health of the Exchanges:

Enrollment is down.

A new [report](#) out of CMS finds that enrollment in the Exchanges has dipped by over 1 million, according to the latest data. Despite the decrease, CMS has also cut funding by \$26 million for the Exchanges' enrollment-assistance navigator program.

Insurers are nervous.

Many of the safeguards integral for insurers on the Exchanges have been removed. Some, like the [risk adjustment payments](#) which helped lighten the burden of covering more costly patients, were initially frozen indefinitely. This could erode insurer confidence and contribute to the [trend](#) of declining participation. Premium spikes of up to 30% have been seen this year, resulting in many individuals being priced-out of the market. America's Health Insurance Plans has [predicted](#) premium hikes (albeit more modest ones) on the Exchanges for 2019.

Destabilization is likely to continue.

The Trump Administration will likely continue to make policy changes that undermine the ACA. The President has [counseled](#) the GOP to "Just remember, this is not our bill, this is their bill." Indeed, newly-permitted [association health plans](#) and other limited-coverage offerings will likely siphon the healthier, less risk-averse away from the Exchanges altogether.



Trump vs Big Pharma: Will He Bring Prices Down?

Since the announcement of the President's Blueprint to Lower Drug Prices, six U.S. based pharmaceutical companies are canceling planned price increases or reducing the current prices. The White House and HHS Secretary Alex Azar have touted the modest wins as a changing tide with more to come but what seems like submission to Presidential gravitas may not actually be so. Critics say the drug makers' concessions aren't evidence of systemic change because the reductions are both temporary and on unpopular drugs that don't threaten companies' profit margins. Has the bully pulpit made a lasting impression on drug prices? Dive into the details below.

In the past three weeks, [Gilead](#), [Merck](#), [Novartis](#), [Novo Nordisk](#), [Pfizer](#) and [Roche](#) have published policies that rescind or reduce previously announced price hikes. The timing of these announcements appears to be a direct response to [Presidential pressure](#). However, many have suggested the companies are creating the illusion of price reductions to garner praise from the White House. For example, Pfizer is only deferring price hikes, not canceling them. The company is "rolling back" the price of products to what they cost in June. Roche has sustained price increases on its top-selling drugs. In July, they raised the price of a single-use vial of Herceptin, a breast cancer drug to \$1,558, a 3% increase. A 16-milliliter vial of Avastin, another cancer drug, went up by 2.5% to \$3,187. Gilead canceled planned price increases for four drugs, none of which are the company's bestsellers.

Whether these initial price decreases will be sustained remains to be seen. The President has held to keeping this topic a part of national conversation and has alluded to [exploring options](#) outside of the Blueprint to guarantee further results.



Policy Makers Explore Changes to Stark Law

The Stark Law has been garnering the attention of policy makers. [Roundtable discussions](#) on regulatory burdens, a recent [hearing](#), a [Request for Information](#) from CMS and an [article](#) from two former Secretaries of the Department of Health and Human Services (HHS), have all advocated for changes to Stark. While legislative activity on Stark Law will be narrow this year, a comprehensive reform package is expected to be filed early in 2019. Changes to modernize Stark will help promote participation in alternative payment models and accelerate the shift towards value-based care. Below are key excerpts from recent efforts to reform Stark.

House Ways and Means Committee Hearing

Health Subcommittee Chairman Peter Roskam (R-IL) argued, “we need to update the laws to give providers an easing of burdens and give CMS more flexibility to supply waivers to these providers who get into these high value arrangements.”

Request for Information (RFI)

CMS Administrator Seema Verma stated, “dealing with the burden of the physician self-referral law is one of our top priorities as we move towards a health care system that pays for value rather than volume.” The Agency seeks comments on “the need for revisions or additions to exceptions to the physician self-referral law, and terminology related to alternative payment models and the physician self-referral law.” AHPA is drafting comments in response to this RFI.

Former HHS’ Secretaries Kathleen Sebelius and Tommy Thompson

On their [article](#) about Stark Law, the Secretaries noted, “we need a combination of legislation to provide greater clarity and to make exceptions permanent, and to revisit regulations, safe harbors, exceptions and guidance to allow for holistic value-based solutions.”



340B Update

Last week, the lawsuit filed by 340B hospitals challenging the nearly 30% payment cut to certain Medicare Part B drugs was [dismissed](#) in the U.S. Court of Appeals. The Court of Appeals affirmed the [District Court's determination](#) that the case had a “lack of subject-matter jurisdiction” due to the plaintiffs failing to present a claim to the HHS Secretary before filing the suit. The plaintiffs [unsuccessfully argued](#) that filing comments in the informal rulemaking process was enough to satisfy the presentment requirement. The Court disagreed and did not consider the merits of the plaintiffs' case in their opinion. The American Hospital Association has already [indicated](#) that they plan to promptly refile.

Medicaid Benefits Restored in Kentucky

In the [last policy brief](#), we discussed Governor Bevin's cancellation of Medicaid vision and dental benefits for thousands of Kentuckians after his desired work requirements' waiver was invalidated. After sharp criticism, Kentucky has now reinstated those benefits and [committed](#) to pay any eligible vision or dental claims made during the gap in coverage. This is welcome news for many providers who were left [reeling](#) by the cuts' abruptness. Kentucky is now [seeking additional comments](#) on the implementation of work requirements in Medicaid.



A Look at The Federal Register

Guidance for Industry on Labeling for Biosimilar Products. The U.S. Food and Drug Administration (FDA) released a [final guidance](#) that provides an overview of the FDA's recommendations for biosimilar product labeling. It is intended to clarify properly labeling to the industry for FDA approval.

CMS Releases Proposed Medicare Outpatient Payment Rule for CY 2019. The [proposed rule](#) increases payment rates by 1.25% in CY 2019. The rule also includes several [site-neutral payment policy proposals](#) and payment reductions to 340B hospitals. Comments are due September 24th. A CMS fact-sheet of the rule is available [here](#).

IN OTHER NEWS

[Blow to PBMs: Trump Administration Mulling Overhaul to Safe Harbor](#) – Fierce Healthcare

[The FDA's Plans to Open Up the Over-The-Counter Market](#) – Stanford Law

[Trump Administration Shutting Down Practice-Guidelines Clearinghouse](#) – STAT News

[ER Doctors Sue Anthem Over 'Dangerous' Policy Denying Coverage](#) – Washington Examiner

[The Future of Health Care: The Bipartisan Path \(Video\)](#) – The Bipartisan Policy Center