AHLA PG Briefing

Navigating Regulatory Changes Faced by Medicare Part D and Medicare Advantage Plans under CMS' May 2019 Final Rule

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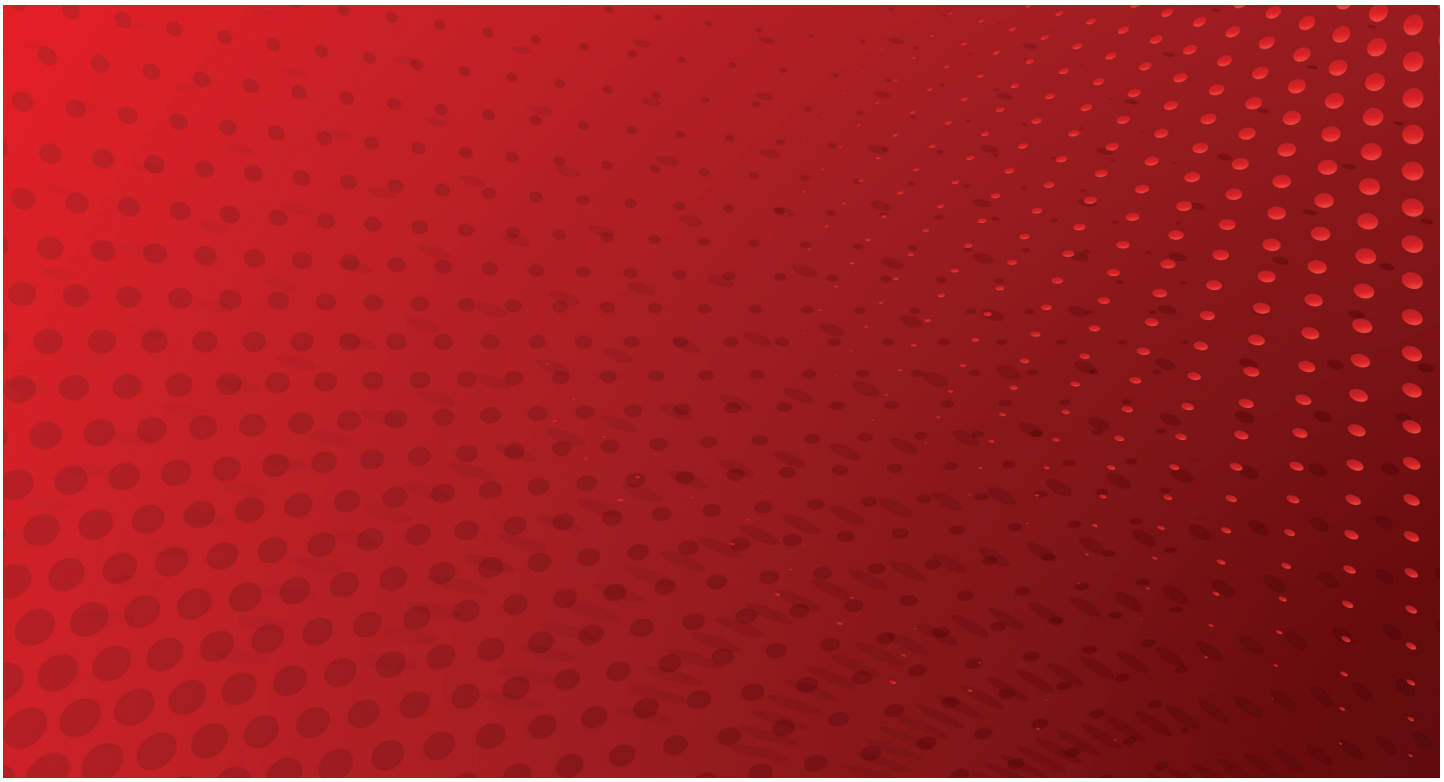

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The Centers for Medicare & Medicaid Services' (CMS') May 2019 Final Rule entitled *Modernizing Part D and Medicare Advantage To Lower Drug Prices and Reduce Out-of-Pocket Expenses* (May 2019 Final Rule) is the latest in a series of steps that the Trump administration has taken to lower drug prices and increase transparency. This article sheds light on how the May 2019 Final Rule builds upon and strengthens prior legislation related to drug pricing and transparency, and how those changes impact Part D and Medicare Advantage (MA) plans. Also discussed is how the May 2019 Final Rule provides MA plans with additional flexibility in plan design and cost management by enhancing supplemental and telehealth benefits, which is important to help MA plans manage costs for its rapidly growing membership. Lastly, consistent with CMS' long-standing mission to reduce fraud, waste, and abuse in the health care system, this article discusses how the May 2019 Final Rule addresses payment integrity issues.

Medicare Part D: Controlling Costs and Increasing Transparency

Lowering drug prices and out-of-pocket costs continues to be a signature issue of the Trump Administration. *American Patients First: The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs* (May 2018), offers an array of strategies to address a number of difficult issues identified by the administration related to the cost of prescription drugs in the United States, including high list prices, overpayment by seniors and government programs due to lack of the latest negotiation tools, high and rising out-of-pocket costs for consumers, and foreign governments "free-riding" off of American innovation.[1] Since then, the administration has taken a number of steps designed to lower drug prices.

By way of example, and perhaps most notably, in February 2019, the Department of Health and Human Services (HHS) Office of Inspector General (OIG) issued proposed changes to the Anti-Kickback Statute safe harbor regulations which, if implemented, would change dramatically the use of rebates in Medicare Part D and Medicaid

[1] https://www.hhs.gov/sites/default/files/AmericanPatientsFirst.pdf

Managed Care.[2] The proposed rule would explicitly exclude from the regulatory definition of a "discount" eligible for safe harbor protection reductions in price or other remuneration from a manufacturer of prescription pharmaceutical products to Part D plans, Medicaid Managed Care plans, or their pharmacy benefit managers (PBMs). Instead, the proposed rule would create two new safe harbors for point-of-sale price reductions which flow directly to enrollees and certain service fees paid by manufacturers to PBMs. While the possible changes to the safe harbor regulations were initially proposed to be effective in 2020, an April 5, 2019 memo from CMS Administrator Seema Verma makes clear that CMS understands that there will need to be much more guidance—and time—for plans to implement any changes to the safe harbor regulations. The Trump administration's spring regulatory agenda, released May 22, 2019, indicates that any changes may not be issued until late fall 2019.[3]

The May 23, 2019 Final Rule

On May 23, 2019, CMS released a final rule entitled *Modernizing Part D and Medicare Advantage To Lower Drug Prices and Reduce Out-of-Pocket Expenses* intended to support both MA and Part D plans' negotiation for lower drug prices and, in turn, reduce out-of-pocket costs for enrollees.[4] The May 2019 Final Rule, however, stops well short of the rule proposed by CMS on November 30, 2018.[5] CMS notably chose not to implement a redefinition of "negotiated price" as the lowest possible payment to a pharmacy, although the agency explained the policy remains under consideration.

CMS similarly abandoned its proposals to allow the broader use of prior authorization and step therapy for protected class drugs and declined to finalize a proposal to allow Part D plan sponsors to exclude from their formularies protected class drugs that

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[2] Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees, 84 Fed. Reg. 2340 (Feb. 6, 2019).
[3] https://www.reginfo.gov/public/do/eAgendaMain?operation=OPERATION_GET_AGENCY_RULE_LIST&currentPub=true&agencyCode=&showStage=active&agencyCd=0900&Image58.x=29&Image58.y=2
[4] 84 Fed. Reg. 23832 (May 23, 2019).
[5] 83 Fed. Reg. 62152 (Nov. 30, 2018).

experience price increases beyond the rate of inflation or that represent only a new formulation of an existing drug. The May 2019 Final Rule instead codifies long-standing Part D policy, allowing Part D plan sponsors to impose prior authorization and step therapy for five of the six protected classes, but only for enrollees first starting the protected class drug.[6] For antiretroviral medications, prior authorization, step therapy, and indication-based formulary design continue to be prohibited.[7]

The May 2019 Final Rule, however, does include a number of measures to further transparency regarding drug prices. It incorporates new requirements into the Part D regulations to implement the 'Know the Lowest Price Act of 2018' (Pub. L. 115–262), which prohibits "gag clauses" in pharmacy contracts.[8] It does so by amending the pharmacy contracting requirements at 42 C.F.R. § 423.120 (a)(8)(iii) to add a paragraph (iii) that provides that a Part D sponsor may not prohibit a pharmacy from, nor penalize a pharmacy for, informing a Part D plan member of the availability of a lower-cost cash price for the prescribed medication than the price that would be charged to obtain the same medication through the enrollee's Part D plan. Under the Final 2019 Part D Rule, sponsors also must include information regarding negotiated price increases and lower cost therapeutic alternatives in their enrollees' explanation of benefits.

Finally, the rule implements provisions requiring Part D plan sponsors to implement by January 1, 2021 an electronic real-time benefit tool (RTBT). It must be able to: (1) integrate with at least one prescriber's electronic prescribing system or electronic health record and (2) provide complete, accurate, timely, and clinically appropriate patient-specific real-time formulary and benefit information (including cost, formulary alternatives and utilization management requirements).[9] Reflecting the possible challenge ahead in implementing this regulatory mandate, CMS concedes that

[6] Part D sponsors must include on their formularies all Part D drugs in six protected categories or classes: (1) antidepressants; (2) antipsychotics; (3) anticonvulsants; (4) immunosuppressants for treatment of transplant rejection; (5) antiretrovirals; and (6) antineoplastics. *See* Social Security Act Section 1860D-4(b)(3)(G).
[7] *See* 42 C.F.R. § 423.120 (vi)(C).
[8] *See* 42 C.F.R. § 423.120 (a)(8).
[9] 42 C.F.R. § 423.160(b)(7).

there are currently no industry-wide electronic standards for RTBTs. CMS hopes, however, that the adoption of RTBT will further price transparency, lowering both overall drug costs and patients' out-of-pocket costs, and improve medication adherence.[10]

Although largely focused on Part D, the May 2019 Final Rule also affirms the authority of MA plans to implement step therapy programs for Part B drugs.[11] While MA plans must already disclose any Part B step therapy requirements in the Annual Notice of Change (ANOC), plans now also must establish policies and procedures to educate and inform health care providers and enrollees specifically concerning step therapy policies.[12] MA plans also must implement a number of beneficiary protections paralleling those found in Part D, including the following: (1) implementing a pharmacy and therapeutic (P&T) committee consistent with Part D requirements;[13] (2) prohibiting the inclusion in step therapy protocols of drugs that the plans do not cover or that are supported by an off-label indication, unless supported by widely used treatment guidelines or best-practice clinical literature;[14] and (3) ensuring that MA plan enrollees have timely access to all medically necessary Part B medication, and shortening adjudication timeframes to be closer to those for Part D coverage determinations and reconsiderations.[15]

The April 16, 2018 Final Rule

The May 2019 Final Rule follows the April 16, 2018 final rule entitled *Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Program, and the PACE Program* (the April 2018 Final Rule), in which CMS promulgated a number of measures intended to address drug costs, including creating additional opportunities for

[10] *See* 84 Fed. Reg. at 23848-49.
[11] 42 C.F.R. § 422.136.
[12] *See* 42 C.F.R. § 422.136(a)(2).
[13] 42 C.F.R. § 422.136(b).
[14] 42 C.F.R. § 422.136(c), (d).
[15] 42 C.F.R. §§ 422.568, 422.570, 422.584, 422.572, 422.590, 422.681, 422.619.

Part D plan sponsors to substitute generic for brand drugs, clarifying the implementation of medical necessity formulary tiering exceptions, and granting plan sponsors new flexibility in plan benefit design.[16] The April 2018 Final Rule, however, deferred action on CMS' proposal to pass through pharmaceutical manufacturer rebates at the point-of-sale, a proposal which generated 1,400 responses to the agency.

In order to promote the rapid substitution of generic for brand drugs, the April 2018 Final Rule provided Part D plan sponsors with greater flexibility to make mid-year substitutions without prior agency approval. Plan sponsors may now immediately replace branded drugs with *newly-approved* generics (or make changes to their preferred or tiered cost-sharing status), if the generic drug was not available on the market at the time the Part D sponsor submitted its initial formulary for approval. The generic drug must be placed on the same or lower cost-sharing formulary tier and with the same or less restrictive utilization management criteria as the branded drug it replaces. The transition process (pursuant to which enrollees receive a temporary supply of drugs when their drugs cease to be on a plan's formulary) is no longer applicable when the plan sponsor substitutes a generic drug for a brand drug on its formulary. As a result, enrollees will no longer qualify for a "transition fill" when their branded drug is replaced on the formulary by a generic equivalent.

The April 2018 Final Rule also clarified tiering exceptions, the subject of some confusion—particularly with regard to generic drugs, given that many formularies have multiple generic tiers and tiers with a mix of brand and generic drugs. The April 2018 Final Rule clarified that plan sponsors may limit the availability of tiering exceptions for brand and generic drug types to the preferred tier that contains the same type of alternative drugs (that is, brand or generic). Plan sponsors are not required to offer a tiering exception for a brand-name drug or biological product to a preferred cost-sharing level that applies *only* to generic alternatives. For non-preferred generic drugs, plan sponsors are required to offer a tiering exception both when the lower tier contains a mix of brand and generic alternatives and when the preferred generic alternative is on a dedicated generic tier. If the preferred alternative sits on more than one tier, the cost-

[16] *See* 83 Fed. Reg. 16440 (April 16, 2018).

sharing for any approved tiering exception must be assigned at the lowest applicable tier.

Medicare Advantage: Managing Rapid Growth and Legal Risk

While the Part D program looks to manage growing drug prices, perhaps the greatest challenge and opportunity for MA plan sponsors is the rapid growth of the program. In 2004, approximately 13% of Medicare beneficiaries, or 5.3 million people, were enrolled in MA. In 2019, that number has grown to more than a third of all Medicare beneficiaries, or 20 million people, with some predictions that that by 2040, MA could capture 70% of all Medicare beneficiaries, or an estimated 60 million people.[17] Further contributing to the growth of the program, MA plans expect increased enrollment of individuals with end-stage renal disease (ESRD), beginning in 2021 as a result of the 21st Century Cures Act (PL 114-255).[18] While CMS has worked to update the ESRD payment methodologies for MA plans, an influx of ESRD enrollees, often with high health care expenditures and complex health care needs, will be challenging to MA plans, which will be exacerbated given the increasing rates of both incidence and prevalence of ESRD in the United States.[19]

Supplemental and Telehealth Benefits

In response to the growth in the MA program, CMS has offered MA plans new tools to help keep their growing number of enrollees healthy, while stewarding health care resources. Notably, CMS has introduced a new level of flexibility for MA plans offering supplemental benefits. MA plans are permitted to offer supplemental benefits to

[17] *See e.g.*, https://dashealth.com/dr-news-item/medicare-advantage-marches-toward-70-penetration.
[18] *See e.g.*, Announcement of Calendar Year (CY) 2019 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter (April 2, 2018), pp. 26, 46; Announcement of Calendar Year (CY) 2020 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter (April 1, 2019), pp. 30-33.
[19] *See* United States Renal Data System, 2018 Annual Data Report, Vol. 2: End Stage Renal Disease, Chapter 1: Incidence, Prevalence, Patient Characteristics, and Treatment Modalities, https://www.usrds.org/2018/view/Default.aspx.

enrollees in addition to those benefits covered by original Medicare. An item or service qualifies as a supplemental benefit if it meets the following criteria: (1) it may not be a Medicare Part A or Part B covered service; (2) it must be primarily health related; and (3) the MA plan must incur a non-zero direct medical cost (*i.e.*, not only an administrative cost) in providing the benefit.[20]

With regard to the requirement that a supplemental benefit be primarily health related, CMS did not consider an item or service to be a supplemental benefit if its primary purpose was daily maintenance prior to 2018. However, in the April 2018 Final Rule, CMS expanded its interpretation of the term "primarily health related" to include items and services that "diagnose, prevent, or treat an illness or injury, compensate for physical impairments, act to ameliorate the functional/psychological impact of injuries or health conditions, or reduce avoidable emergency and healthcare utilization."[21] This change was based on research supporting the value of items and services that diminish the impact of injuries and health conditions and thereby reduce the need for emergency and health care services. As a result, MA plans may now design supplemental benefits that enhance beneficiaries' quality of life and improve health outcomes.[22]

Further, beginning in 2020, MA plans may offer a broader category of supplemental benefits to chronically ill enrollees to better tailor benefit offerings, address gaps in care, and improve health outcomes as a result of the Bipartisan Budget Act of 2018 (PL 115-123).[23] Specifically, MA plans may offer an item or service as a Special Supplemental Benefit for the Chronically Ill (SSBCI) that is not primarily health related, so long as the enrollee meets the statutory definition of chronically ill and the item or service has a reasonable expectation of improving or maintaining the health or overall function of the enrollee as it relates to the chronic condition or illness. MA plans have broad discretion

[20] *See* Medicare Managed Care Manual Ch. 4 § 30.1.
[21] *See* Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program, 83 Fed. Reg. 16440, 16480-16485 (April 16, 2018); Final Call Letter for CY 2019 (emphasis added); HPMS Memo, Reinterpretation of "Primarily Health Related" for Supplemental Benefits (April 27, 2018); HPMS Memo, Reinterpretation of the Uniformity Requirement (April 27, 2018).
[22] *See* Final Call Letter for CY 2020, pp. 187-88.
[23] *See* 83 Fed. Reg. at 16481-16485; Final Call Letter for CY 2020 at 188-91; HPMS Memo, Implementing Supplemental Benefits for Chronically Ill Enrollees (April 24, 2019).

in developing the items and services to be offered as SSBCI. Additionally, MA plans are not required to comply with Medicare's uniformity requirements in offering SSBCI, but rather, may vary or target SSBCI as they relate to an individual enrollee's specific medical condition and needs.[24]

MA plans also can provide "additional telehealth benefits" to enrollees starting in 2020, and can treat such benefits as basic benefits.[25] CMS permits MA plans to offer Part B benefits via telehealth if (1) enrollees have the option to receive the covered benefit in person and are advised of this option; (2) the telehealth benefits are provided by contracted and credentialed providers, who comply with state licensing requirements; and (3) the MA plan provides CMS information about the cost, methods, and effectiveness of the telehealth benefit upon request. CMS has granted MA Plans the discretion to determine what benefits are clinically appropriate to offer as telehealth benefits. Plans also may offer telehealth benefits as supplemental benefits if they opt not to comply with the preceding requirements or if a benefit is not covered by Part B (e.g. video dental consultation).

Payment Integrity

In an attempt to adapt to the changing landscape, CMS has taken additional measures to improve payment integrity in the MA and Part D program through new preclusion list requirements issued in the April 2018 Final Rule and clarified by the May 2019 Final Rule.[26] MA and Part D plans cannot make payments to prescribers, individuals, or entities who are on CMS' preclusion list, and must remove any contracted provider in

[24] *Id*.
[25] *See* Medicare and Medicaid Programs; Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Programs of All-Inclusive Care for the Elderly (PACE), Medicaid Fee-For-Service, and Medicaid Managed Care Programs for Years 2020 and 2021, 84 Fed. Reg. 15680, 15929 (April 16, 2019); 42 C.F.R. §§ 422.100, 422.135, 422.252, 422.254, and 422.264.
[26] *See* 83 Fed. Reg. 16440 (April 16, 2018); 84 Fed. Reg. 15680-81, 15780-15797 (April 16, 2019). *See also* CMS Preclusion List website: https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/PreclusionList.html.

their network that is listed on the preclusion list as soon as possible. CMS' preclusion list includes providers who:

- Are currently revoked from Medicare, are under an active reenrollment bar, or CMS has determined that the underlying conduct that led to the revocation is detrimental to the best interests of the Medicare program; or

- Have engaged in behavior for which CMS could have revoked the prescriber, individual, or entity to the extent applicable if they had been enrolled in Medicare, and CMS determines that the underlying conduct that would have led to the revocation is detrimental to the best interests of the Medicare program. Such conduct includes, but is not limited to, felony convictions and OIG exclusions.[27]

CMS will provide written notice to an individual or entity of its inclusion on the preclusion list and will provide for appeal rights under Part 498.[28]

CMS made the preclusion list available to MA and Part D plans on January 1, 2019, and began to require plan sponsors: (1) to screen the preclusion list monthly; (2) as of April 1, 2019, to deny claims for items or services furnished by an individual or entity on the preclusion list; and (3) to provide beneficiaries advance notice of their provider's inclusion on the preclusion list and the forthcoming denial of claims. In the May 2019 Final Rule, CMS consolidated the appeals process for individuals and entities on the preclusion list, shortened the timing of additions to the list, clarified the effect of felony convictions on inclusion on the preclusion list, and revised the language plan sponsors must include in provider agreements with respect to nonpayment for services rendered by providers on the preclusion list.

Finally, one of the hottest topics in MA, risk adjustment, has had relevant activity this past year. In September 2018, a U.S. District Court in *UnitedHealthcare Insurance Company v. Azar*[29] struck the MA overpayment regulation[30] and held that it was

[27] *See* 42 C.F.R. §§ 422.2, 423.100.
[28] *See* 42 C.F.R. §§ 422.222, 423.120.
[29] *UnitedHealthcare v. Ins. Co. v. Azar*, 330 F. Supp. 3d 173 (D.D.C. Sept. 7, 2018).
[30] 42 C.F.R. § 422.326; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs, 79 Fed. Reg. 29844, 29844-968 (May 23, 2014).

arbitrary for CMS to treat any incorrect diagnosis code as an overpayment, when for risk adjustment data validation (RADV) audits only errors above a certain threshold are penalized (the fee-for-service (FFS) adjustor). Perhaps anticipating this ruling, CMS issued a proposed rule on November 1, 2018 that would introduce significant changes to RADV audits.[31] CMS proposed to eliminate the FFS adjustor from RADV audit findings and solicited comments regarding the agency's methodology for calculating an extrapolated payment error for RADV audits.[32] CMS then moved for reconsideration in *United Healthcare v. Azar* based on the new studies the agency relied upon in the November 1, 2018 proposed rule and that the agency asserts show that the diagnosis errors in fee-for-service claims data do not lead to systemic payment errors in the MA program.[33] After releasing the data for review, CMS extended the comment period for the RADV provisions of the November 1, 2018 proposed rule twice, and comments are now due August 28, 2019.[34] The repeated extension of the comment period reflects the complexity of risk adjustment and its importance to MA plans and their ability to bear the cost of health care for enrollees with chronic conditions and complex health care needs.

[31] *See* Medicare and Medicaid Programs; Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Program of All-Inclusive Care for the Elderly (PACE), Medicaid Fee-for-Service, and Medicaid Managed Care Programs for Years 2020 and 2021, 83 Fed. Reg. 54892 (Nov. 1, 2018).
[32] *See* 83 Fed. Reg. at 55038.
[33] *See* Fee for Service Adjuster and Payment Recovery for Contract Level Risk Adjustment Data Validation Audits (Oct. 26, 2018), https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-Risk-Adjustment-Data-Validation-Program/Other-Content-Types/RADV-Docs/FFS-Adjuster-Excecutive-Summary.pdf.
[34] *See* 83 Fed. Reg. 66661 (Dec. 27, 2018); 84 Fed. Reg. 18215 (Apr. 30, 2018).