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CMS Releases Final Rule Aimed at Lowering Drug Prices and Reducing Out-of-Pocket Spending

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Since mid-2018, the Centers for Medicare and Medicaid Services (CMS) has been implementing sections of the American Patients First Blueprint, President Trump's plan to lower drug prices and reduce patient out-of-pocket spending. The blueprint calls on the US Department of Health and Human Services, CMS and the US Food and Drug Administration to take action in four areas addressing the challenges in the prescription drug market:

- Improving competition
- Fostering better negotiations between payers and drug manufacturers
- Incentivizing lower list prices for prescription drugs
- Lowering out-of-pocket costs

The latest release from CMS, posted on May 18, 2019, is the final rule Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses. In implementing the final rule, CMS made major policy shifts, but held back on several Part D proposals that the agency originally floated in early 2019.

Summary of Key Policies

In this final rule, CMS finalizes policies that will:

- Codify existing guidance allowing Part D sponsors to use prior authorizations (PA) and to apply step therapy (ST) edits for new starts of protected class drugs (except antiretrovirals)
- Allow Part D sponsors to exclude from formulary placement interchangeable biological products[1] in addition to the current exemption for therapeutically equivalent generic drugs
- Allow MA Plans to use ST/PA to help ensure cost-effective and clinically appropriate care
- Make changes to Part D e-prescribing standards that improve the cost-effectiveness of the Part D benefit
- Require the inclusion of negotiated drug pricing information and lower-cost alternatives in the Part D Explanation of Benefits in order to provide enrollees with greater transparency into drug prices in the hopes of encouraging lower costs

In this final rule, CMS elected to not finalize proposed policies that would have:

- Allowed Part D sponsors to exclude new formulations of single-source drugs or biologicals from formulary placement
- Allowed Part D sponsors to exclude from formulary placement single source drugs or biologicals in a protected class whose price increased in a year at a rate greater than the Consumer Price Index for Urban Consumers (CPI-UC)

Providing Plan Flexibility to Manage Protected Classes

Part D sponsors are required to include all covered Part D drugs in six categories of clinical concern (the protected class policy). These categories comprise anticonvulsants, antidepressants, antineoplastics, antipsychotics, antiretrovirals and immunosuppressants for the treatment of transplant rejection. Current regulations allow sponsors to exclude protected class drugs from their formularies when:

- There are therapeutically equivalent generic drugs available.
- Utilization management edits are applied for safety reasons.
- There is a medical and scientific process that permits public notice and comment determines that the drug should be excluded from the formulary[2].

While CMS believes that ongoing initiatives, including beneficiary access protections, prevent enrollees from inappropriate delays in access to drugs, the agency continues to be concerned that costs for protected class drugs covered by

the Part D program have increased because of the lack of formulary competition.

Prior Authorization/Step Therapy

This final rule codifies existing policy allowing sponsors to use PA and to apply ST edits for new starts of protected class drugs (except antiretrovirals). Sponsors may use PA/ST only to determine if a drug's intended use is for a protected class indication and that the drug is being used in a clinically appropriate manner, and to promote utilization of preferred formulary alternatives or a combination thereof. To prevent risk of harm to patients, including the risk of interrupting ongoing and effective treatment, PA/ST may only be used for new starts.

While PA/ST may not be applied to ongoing courses of therapy, sponsors may still apply PA and other tools for all potential Part D drugs in order to determine if the drugs are covered under Part D for both new starts and for existing therapy, and for drugs with a high likelihood of being excluded from Part D. CMS notes that PA requirements may differ between protected class and non-protected class indications.

PA/ST criteria must be clinically based. Providers are allowed to request formulary exemptions in clinical situations where access to a specific agent is required. Additionally, CMS will review Part D sponsors' PA/ST plans to avoid potential discrimination and adverse patient selection.

Formulary Exceptions for New Drug Formulations

CMS considered two additional exceptions to current regulations that would have allowed Part D sponsors to exclude from their formularies (1) interchangeable biosimilars and single source drugs, and (2) new formulations of single-source drugs or biologicals that have "the same active ingredient and moiety that does not provide a unique route of administration." (84 Fed. Reg. 23,834)

CMS will allow Part D sponsors to exclude from formulary placement, subject to CMS review and approval, interchangeable biological products (when such products are approved by FDA) in addition to the current exemption for therapeutically equivalent generic drugs.

CMS agreed with stakeholders that allowing Part D sponsors to exclude new formulations of single-source drugs or biologicals from formulary placement could leave beneficiaries without access to a drug if the old formulation is no longer available. CMS elected to not finalize this exception.

High-Cost Changes

CMS elected to not allow Part D plans to exclude from formulary placement single source drugs of biologicals in a protected class whose price increased in a year at a rate greater than the CPI-UC.

While CMS believes that clinically based and cost-based restrictions on formulary placement can co-exist, and that formulary exemptions based on price are not a

"departure from current policy," (84 Fed. Reg. 23,843) stakeholder comments convinced CMS that it was best to more closely consider ways to encourage manufacturers to actively lower drug prices on their own—rather than being forced to do so through administrative policy making.

Step Therapy under Medicare Advantage Prescription Drug Plans and Medicare Advantage Plans for Part B Drugs

Prior to 2018, CMS had interpreted its existing authorities to prohibit MA and MA-Prescription Drug Plans (hereafter, plans) from applying ST to claims from their beneficiary population, believing that it effectively restricted coverage of services. Recognizing that ST can be effective in controlling the cost of prescription drugs and devices and lowering out-of-pocket costs for beneficiaries, CMS issued guidance in August 2018 changing its prior interpretation to allow plans to apply ST subject to certain beneficiary protections.

Under its revised interpretation, now codified in this final rule, CMS considers the use of ST to be a reasonable and necessary determination and not a coverage restriction. Therefore, plans can use ST to help ensure cost-effective and clinically appropriate care.

The final rule also applies to MA PPOs—except that PPOs may not apply ST to out-of-network beneficiaries.

Cross-Benefit Step Therapy Programs

In addition, beginning in plan year 2020, plans which also provide a Part D drug benefit along with their MA benefit, may also require ST of a Part B drug before a Part D drug in a protected class is used.

CMS believes that beneficiary out-of-pocket costs will be reduced through the use of more cost-effective, clinically appropriate drug therapies. And because the final rule requires savings from ST to be included in future years' bids, ultimately MA premiums will go down.

Step Therapy Requirement Development under Part B

To reduce the risks that could accompany the application of ST, the final rule allows MA plans to use ST for Part B drugs, but only under a specific set of parameters.

In order to ensure medically appropriate implementation of ST, ST plans must be developed by a pharmacy and therapeutics (P&T) committee and be literature based. By consulting with physicians and other practitioners (who are independent of the plan itself), plans can ensure that their ST requirements are based on reasonable clinical evidence. P&T review of other utilization management tools is not required.

In addition, decisions must be documented, and P&T committees must maintain a record of their decisions that is available to CMS (however, the record is not public). All ST requirements are to be reviewed by CMS annually.

Plans are also expected to work with providers to adopt best practices that can streamline workflows and ensure continued access to benefits. This could include electronic processes to administer the programs.

CMS plans to issue additional subregulatory guidance addressing disclosure and communication of ST requirements to providers and beneficiaries.

Beneficiary Protections

As mentioned previously, MA plans must continue to cover all medically necessary Part B medications. ST may not be used as an "unreasonable barrier" (84 Fed. Reg. 23,846) to coverage or to otherwise limit benefits. The final rule states that ST requirements may not be stricter than existing ST requirements in LCD/NCD (if any), and that if ST does not exist in a policy or if the policy does not preclude ST, a plan may apply ST requirements (subject to all the other restrictions in the final rule).

To mitigate any risk to beneficiaries currently using a Part B drug that may otherwise be subject to ST, plans may only apply ST to new starts. Plans must identify if a beneficiary has used a Part B drug within the prior 365 days. If a beneficiary has used a Part B drug in the previous 365 days, the beneficiary's ongoing use is not subject to ST. This requirement applies to existing enrollees as well as new enrollees, and to beneficiaries who switch plans.

Furthermore, ST cannot require a beneficiary to use a drug off-label as a step unless the off-label use is widely recognized in guidelines and supported by literature that CMS considered to reflect best practices. At this time, CMS has not indicated which, if any, guidelines would meet this criteria. Under no circumstances may ST require the use of a non-covered drug as a step.

Plans may modify their ST requirements mid-year but only in accordance with existing rules about changes to plan rules.

In order to protect beneficiary access, organizational determinations for Part B drug coverage must be completed within shortened timeframes: 24 hours for expedited organizational determinations, or 72 hours for standard organizational determinations. CMS encourages plans to communicate their determinations as rapidly as possible; under no circumstances may a plan delay these timeframes. Integrated plans (*e.g.*, dual eligible special needs plans) are required to follow the same timeframes.

All organizational determinations must be based on medical necessity, and beneficiaries have the right to appeal negative determinations.

For chemotherapy administration, renal dialysis and skilled nursing, cost sharing under MA may not exceed the cost sharing amounts under Original Medicare. Cost sharing may not exceed 20% for drugs used during the course of chemotherapy administration even if ST is applied.

Role of Providers

In the final rule, CMS walked back from its proposal to require plans to include care

management activities as a part of ST, opting instead to make providers actively responsible for managing patient care. Treating physicians are expected to discuss the impact of ST on patient care and, when needed, request organizational determinations for their beneficiaries when they feel ST may be clinically inappropriate. CMS expects that requiring treating physicians to closely monitor patients and advocate with plans on their behalf will be an efficient way to manage beneficiary care.

Monitoring of Step Therapy Requirements

CMS will monitor complaints and the outcomes of organizational determinations and appeals to ensure that plans are appropriately developing and applying ST requirements.

Prohibiting Pharmacy Gag Clauses

The final rule prohibits Medicare Part D plan sponsors from restricting their network pharmacies from informing their Part D plan enrollees of the availability of prescription drugs at a cash price that is below what the enrollee will be charged (either the cost-sharing amount or the negotiated price when it is less than the enrollee's cost-sharing amount) for the same drug under the enrollee's Part D plan.

Beginning with plan years starting on or after January 1, 2020, pharmacies will no longer be prohibited from providing Part D enrollees with information about cash pay prices that, in some cases, may result in lower out-of-pocket spending for beneficiaries.

CMS commits to evaluating the impact of this change on the Part D program and indicates that it may propose future regulations to address any risks to the program or to enrollees.

Part D E-Prescribing Standards

In an effort to ensure that prescribing physicians have access to real-time information on beneficiary-specific drug coverage and cost data CMS is requiring Part D plans to provide "real time benefit tools" (RTBT) as a part of physician electronic health records and e-prescribing systems.

RTBT must provide information on the drug that the provider intends on prescribing, enrollee cost-sharing information, comparable information on formulary alternatives, and patient-specific utilization requirements that may or may not have been satisfied at the time the prescription is written. RTBT do not need to include negotiated pricing; however, CMS strongly recommends that price information be included to the extent possible.

By the start of plan years beginning on or after January 1, 2020, Part D plans will be required to implement at least one RTBT "of their choosing." (84 Fed. Reg. 23,877) CMS believes that by doing so, treating physicians will have access to "accurate, timely and clinically appropriate patient-specific real-time formulary and benefit information (including cost, formulary alternatives and utilization management

requirements." (84 Fed. Reg. 23,833) CMS elected to not require a standardized system that all plans would be required to use, instead deferring that decision until an industry standard emerges. Plans will be held responsible for making the RTBT available, but not for ensuring that their prescribers actually use the system.

Part D Explanation of Benefits

Currently, Part D sponsors must provide enrollees with an explanation of benefits (EOB) no later than the end of the month following any month in which the enrollee utilized his or her prescription drug benefit. Beginning with plan years starting on or after January 1, 2021, sponsors must include negotiated price increases and lower-cost therapeutic alternatives in their beneficiaries' Part D EOBs.

As is currently required, the EOB would display the price paid by the beneficiary, plan and any other payer for prescribed Part D drugs. Under this new policy, the EOB must also display the percentage increase in the total cost for each prescription, after the first claim of the current benefit year. This information must be displayed under each medication. EOBs must also include lower-cost therapeutic alternatives determined by the sponsor based on its formulary.

CMS believes this policy will help beneficiaries to engage in discussions with their prescribing physicians regarding the cost of their prescriptions and could encourage the use of lower-cost alternative medicines.

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[1] Currently, the FDA has not approved any interchangeable biological products.

[2] 42 C.F.R. 423.120(b)(2)(vi)