



RIN 0938–AT92. Modernizing Part D and Medicare Advantage To Lower Drug Prices and Reduce Out-of-Pocket Expenses. 83 Federal Register 231 (November 30, 2018) (“Proposed Rule”)

Dear Administrator Verma:

On behalf of the Regulatory Relief Coalition (the “Coalition”), we are writing to urge CMS to refrain from finalizing those provisions of the Proposed Rule that would authorize Medicare Advantage Organizations (MAOs) to institute step therapy restrictions (“Fail First Coverage Restrictions”) on access to Part B drugs and biologicals and to expand the use of Fail First Coverage Restrictions for Part D “protected class” drugs and biologicals.

The Regulatory Relief Coalition is a group of ten major professional organizations focused on maintaining Medicare patient access to medically necessary services, through the reduction in administrative burdens, including Prior Authorization (PA), that divert physician focus away from patient care. Extensive use of PA by MAOs is creating significant barriers to access for MA enrollees and, for this reason, over the past year and a half, the Coalition has urged CMS to increase its oversight of MAOs’ use of PA to conduct pre-service reviews. Our request for additional oversight of, and the issuance of guidance to, MAOs has been echoed by virtually every medical specialty association, almost 50 patient organizations, and over 100 members of Congress on both sides of the aisle. We are greatly concerned that instead of responding to those calls for oversight and guidance, CMS issued the Proposed Rule expanding the authority of MAOs to institute pre-service denials, using Fail First Coverage Restrictions.

Fail First Coverage Restrictions are essentially PA on steroids: Rather than conducting pre-service reviews and denying coverage for physician’s prescribed services after review by a MAO physician, Fail First Coverage Restrictions categorically deny coverage for a drug prescribed by a contracted physician unless and until other “preferred” or less costly drug(s) are tried first. Fail First Coverage Restrictions differ from other PA coverage restrictions only insofar as authorization is categorically denied in the first instance.

We are concerned that CMS has proposed to specifically authorize PA/Fail First requirements with a potentially significant impact on MA enrollees’ access to both Part B drugs and Part D “protected class” drugs, without first issuing much needed guidance to MAOs regarding the appropriate use of PA and without establishing adequate oversight mechanisms, as requested by the Coalition. In fact, under the Proposed Rule, MAOs are not even required to submit PA/Fail First coverage limits on Part B drugs to CMS before implementing them; thus, the Proposed Rule would delegate virtually unfettered authority to MAOs to establish PA/Fail First restrictions on access to Part B drugs: .

Nor does the Proposed Rule comport with the transparency principles supported by the Coalition – and by the managed care industry itself. While some of the preamble language is comforting, this language is not binding on MAOs, and the Proposed Rule itself fails to require MAOs to adequately inform physicians and other prescribing practitioners of Fail First Coverage Restrictions, requiring only that a MAO must:

*Establish policies and procedures to educate and inform health care providers and enrollees concerning its step therapy policies.*

42 CFR Section 422.136(a) (2)(proposed). Thus, all that is required by the Proposed Rule is that a MAO establish some kind of policy to educate and inform providers and enrollees. The Proposed Rule's language includes no specific requirements regarding what the policy must include or how (or how frequently) Fail First Coverage Restrictions are disseminated either to providers or to beneficiaries. By contrast, the **Consensus Statement on Improving the Prior Authorization Process**<sup>1</sup>, which the Coalition has urged CMS to adopt, urges payers to share PA and similar restrictions on coverage with providers on provider-accessible websites and through at least annual mailings.

The Proposed Rule also fails to reflect the statutory requirement for MAOs to make Fail First Coverage Restrictions and other utilization management controls transparent to potential enrollees. Under the Act, MAO must disclose to each enrollee:

*Rules regarding prior authorization or other review requirements that could result in nonpayment.*

Social Security Act, Section 1852( c) (1)(G). Such disclosure must be in "clear, accurate, and standardized form." No provision in the Proposed Rule implements this requirement with respect to Fail First Coverage Restrictions, and MAOs' current disclosures with regard to their application of other PA requirements are so general as to be essentially meaningless.

In short, we find it disconcerting that the Proposed Rule appears to exacerbate, rather than address, many of the issues related to MAO use of PA. Under these circumstances, we respectfully request that CMS refrain from finalizing those provisions of the Proposed Rule that would expand Fail First Coverage Restrictions for Part D protected class drugs and that would authorize MAOs' imposition of such restrictions on coverage for Part B drugs.

Sincerely yours,

/s/

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Regulatory Relief Coalition

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<sup>1</sup> <https://wwwprod.ama-assn.org/sites/default/files/media-browser/public/arc-public/prior-authorization-consensus-statement.pdf>