

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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MEDICARE PARTS C AND D OVERSIGHT AND ENFORCEMENT GROUP
MEDICARE DRUG BENEFIT AND C & D DATA GROUP

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TO: All Prescription Drug Plan Sponsors and Medicare Advantage Organizations offering Part D (excluding PACE contracts, Cost contracts, and employer-only plans)

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SUBJECT: Compliance and Enforcement Actions Related to Part D Auto-Forwards

Pursuant to 42 CFR §§ 423.568(b), 423.572(a), 423.590(a), and 423.590(d), Part D sponsors are required to process coverage determinations and redeterminations and notify enrollees of those decisions within the timeframes established in regulation. A sponsor's failure to process and notify the enrollee of its determination in the appropriate timeframe constitutes an adverse decision and the sponsor must "auto-forward" the enrollee's request to the Independent Review Entity (IRE) within 24 hours of the expiration of the applicable adjudication timeframe per §§ 423.568(h), 423.572(d), 423.590(c), and 423.590(e). While all auto-forwarded cases represent non-compliance with CMS requirements for timely processing, of particular concern to CMS are plan sponsors that have inordinately high levels of cases that are auto-forwarded due to the plan sponsor's failure to meet the required adjudication timeframes.

As stated in the *Announcement of Calendar Year (CY) 2017 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter*, released April 4, 2016, CMS will continue to increase the level and severity of the compliance and enforcement actions imposed on plans that substantially fail to comply with adjudication requirements for coverage determinations and redeterminations.

CMS will identify sponsors to be issued compliance actions out of those that do not meet the Civil Monetary Penalty (CMP) criteria described below but still have an inordinately high auto-forward rate. Based on currently available data for 2016, CMS expects to issue compliance notices to sponsors that have ten or more IRE cases/appeals, ten or more auto-forwarded cases, and an auto-forward rate of ten or higher per 10,000 members during any quarter in 2016.¹ In

¹ CMS will continue to analyze auto-forward data and may modify this threshold as needed on an annual basis to address changes in industry performance.

2017, CMS will begin effectuating the compliance-to-enforcement escalation process. For example, sponsors that received a Notice of Non-Compliance for the fourth quarter of 2016 and exceed the compliance threshold in the first quarter of 2017 will be issued a Warning Letter, and so on. A sponsor that receives compliance notices over multiple quarters may ultimately be subject to an enforcement action. Also, a sponsor that meets the CMP threshold in any quarter may be subject to a CMP, regardless of its auto-forward compliance letter history.

Pursuant to §§ 423.752(c)(1)(i) and 423.509(a)(4)(ii), CMS has the authority to impose CMPs against sponsors that substantially fail to comply with the requirements to make timely coverage determination and redetermination decisions. Beginning with the first quarter of 2017, CMS will issue CMPs on a quarterly basis to sponsors that fail to meet an established threshold. Based on an analysis of previous year's data, CMS expects that the 2017 outlier threshold will be set at a rate of 15 or more auto-forwards per 10,000 beneficiaries per quarter.² Sponsors with an enrollment size of less than 800, fewer than 10 IRE cases/appeals per quarter, and fewer than 10 auto forwarded cases per quarter are excluded from the analysis.

Through these enforcement and compliance actions, CMS aims to reduce the number of cases auto-forwarded to the IRE due to expiration of the applicable adjudication timeframe, and thereby improving sponsors' timeliness in making coverage and redetermination decisions.

Each sponsor should develop and implement processes that will help it make decisions timely and avoid high levels of cases that need to be auto-forwarded to the IRE. For example, sponsors should monitor their coverage determination and redetermination workload closely and approve requests when the deadlines are quickly approaching rather than missing the deadlines and forwarding the requests to the IRE. Sponsors should also anticipate the increased volume of requests at the beginning of each year and ensure that the appropriate number of staff are available to process the requests.

If you have any questions about this effort, please contact the Part D monitoring mailbox at PartD_Monitoring@cms.hhs.gov.

² See footnote 1.