Cleveland Clinic

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Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8013
Baltimore, MD 21244–1850

RE: CMS-4182-P, 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 – Proposed Rule (RIN 0938-AT08)

Submitted electronically via: Regulations.gov

Cleveland Clinic (CC) is a not-for-profit, integrated healthcare system dedicated to patient care, teaching, and research. Our health system is comprised of a main campus, 10 community hospitals, and 21 family health centers with over 3,500 salaried physicians and scientists. Last year, our system had more than seven million patient visits and over 220,000 hospital admissions.

We appreciate the dedication of the Agency staff on behalf of the Medicare Program and the work they devote to its administration. We believe it is important for hospitals to share information with CMS so the Agency staff has a better understanding of the challenges and practicalities faced by the hospitals regarding proposed changes in policy.

Cleveland Clinic's primary interest in the proposed changes to Medicare Parts C and D are in the impact on the patient. Providing effective, comprehensive care to Medicare beneficiaries is only possible when those beneficiaries can access the drugs and services their healthcare providers prescribe. Policies that create new hurdles or higher costs for beneficiaries impede the ability of clinicians and caregivers to keep patients well.

In particular, Cleveland Clinic remains concerned about the rising costs of prescription drugs for consumers. While premiums have remained relatively stable, CMS has noted that higher prices at the point of sale lead to higher co-pays for Medicare beneficiaries.[1]

We welcome a number of the proposed policy changes to Medicare Advantage and the Part D Drug Benefit Program as they offer flexibilities that benefit patients, providers, and plans alike. We do, however, offer commentary and recommendations about certain proposals. The following are the comments of Cleveland Clinic in respect of the captioned proposed rule.

[1] https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2017-Fact-Sheet-items/2017-01-19-2.html

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Flexibility in the Medicare Advantage Uniformity Requirements

CMS Proposal:
CMS proposes to modify the Medicare Advantage Uniformity Requirements to expand the ability of plans to offer incentives for patients to engage in treatments and behaviors that reduce the burden of chronic disease on patients and the Medicare program. In 2016, Medicare allowed MA plans to begin offering non-cash incentives for compliance with certain screening and wellness visits, so long as the incentives were independent of diagnosis. In the proposed rule, CMS would relax the constraints on these incentive programs to allow for supplemental benefits and increased incentives opportunities (including reduced or eliminated co-pays) for patients with diagnosis of chronic disease, providing those incentives were based on behaviors and not on specific achievements of health goals. Further, the program would prohibit specific penalties levied on patients with chronic disease diagnoses.

Cleveland Clinic Comment:
As strong proponents in the use of financial incentives to encourage wellness, Cleveland Clinic supports these proposed changes and expresses its appreciation to the Agency for taking this important step forward in engaging beneficiaries in their health choices.

A 2009 American Journal of Public Health study (Goldman, 2009) provided evidence that the medical community had long suspected: that bringing five critical health metrics within normal healthy levels could reduce the incidence of chronic disease and reduce overall health care costs, even after accounting for the cost of the preventive medical interventions. At Cleveland Clinic, we helped all beneficiaries of our employee health plan achieve specific measures related to these metrics – LDL Cholesterol less than 130, Hemoglobin A1C less than 7%, BMI of less than 27, blood pressure less than 140/90, and no tobacco use. These efforts have drastically reduced our health care costs, through lowered utilization of Emergency Departments, fewer inpatient days, and improved medication compliance.

The keys to achieving these savings were three-fold: first, we reduced or eliminated co-pays for prevention activities and direct treatment of chronic conditions, such as dietician visits for diabetes patients, blood pressure medications if a patient was 100% compliant with their regimen, and annual wellness and screening visits, among others. We also reduced annual premiums by 10-30% for all beneficiaries who were diagnosed with a chronic condition and were 100% compliant with their treatment plans for that condition, or who were healthy and participated in all of their wellness and screening visits. Finally, we made additional programs and treatments available to patients who were diagnosed with one or more chronic conditions, including personalized weight management coaching and smoking cessation programs for those patients who were diagnosed with obesity or who were tobacco users.

Overall, these changes have saved our self-funded health plan more than $254 million over seven years, even after the cost of additional benefits and the reductions in co-pays and premiums.

We believe that giving MA plans the freedom to more creatively implement their own incentive programs cannot help but improve the health of Medicare beneficiaries and reduce costs. Further, we encourage the Agency to seek creative ways to extend these incentives and benefits to patients

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enrolled in traditional Parts A and B programs, to further improve the health of all Medicare enrollees in the future.

Implementation of the Comprehensive Addiction and Recovery Act (CARA) of 2016 Provisions: Proposed Requirements for the Part D Drug Management Program

CMS Proposal:
For the 2019 plan year, CMS proposes a regulatory framework under CARA for Part D sponsors to implement a voluntary drug management program limiting an at-risk beneficiary's access to opioids to selected prescribers and/or pharmacies.

Cleveland Clinic Comment:
Cleveland Clinic has concerns about the proposal offered by CMS.

Opioid abuse is a significant public health threat in many parts of the country, including Northeast Ohio. Cleveland Clinic is committed to working with other providers and stakeholders to address this epidemic.

Cleveland Clinic supports the intent behind the proposed lock-in programs. Using claims to identify which patients are consuming problematic quantities of opioids is logical, and Cleveland Clinic is glad to see plans proactively use the data available to them.

However, we have concerns that the proposals here could have a restrictive impact on some Medicare beneficiaries and could, in some cases, impede recovery.

The proposed approach to identify at-risk or potentially at-risk beneficiaries would call for CMS or Part D sponsors to use a set of delineated clinical guidelines. The proposed clinical guidelines state that drug management programs should include patients using an average daily morphine milligram equivalent (MME) greater than or equal to 90 mg of opioids for any duration during the most recent six months and either four or more opioid prescribers and four or more opioid dispensing pharmacies *or* six or more opioid prescribers, regardless of the number of opioid dispensing pharmacies.

While we support palliative options for hospice, long-term care, and cancer patients, the 90 mg parameter in the proposed clinical guidelines should also exclude patients prescribed opioids that are FDA-approved for the treatment of opioid use disorder and are being prescribed for that diagnosis in the specific patient. We disagree with the imposition of additional deterrents when effective treatment is already in place for patients with opioid use disorder.

The proposed clinical guidelines also identify patients who are prescribed opioids by multiple prescribers or filling prescriptions at multiple pharmacies, but the time frame for this counting of prescribers/pharmacies is unclear. Although there is some suggestion that filling activity should be assessed over six months, we request CMS clarify the time frame during which assessing prescribing and filling activity begins and ends.

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In addition, Cleveland Clinic is supportive of a marketplace that allows patients to seek and receive the best price for a prescription, while receiving reasonable and courteous customer service at the pharmacy. Particularly for beneficiaries in recovery, the experience of acquiring necessary pain control or medically assisted treatment must be a comfortable process, and beneficiaries should be able to identify the pharmacy that makes sense for them. While CMS has proposed safeguards that would allow a beneficiary to express a preference that should be honored, we are concerned about the impact of limiting access to one facility.

CMS proposes a six-month waiting period from the date of the first Overutilization Monitoring System report identifying a beneficiary as at-risk before allowing a Part D sponsor to limit access to frequently abused drugs. The proposed six-month waiting period is insufficient. Patients who might meet the parameters in the clinical guidelines will have to work with their prescriber to reduce their MME dose and/or change their provider behavior. Dose reduction can be a lengthy and complicated process, and as such we recommend, at minimum, a year-long waiting period.

In general, Cleveland Clinic is concerned about preserving the relationship between providers and patients recovering from opioid addiction. While the intent of the pharmacy lock-in is important, if not executed correctly, it could cause potential damage to the recovery process. Cleveland Clinic urges CMS to make sure this relationship is preserved.

Treatment of Follow-On Biological Products as Generics for Non-LIS Catastrophic and LIS Cost Sharing (42 CFR § 423.4)

CMS Proposal:
CMS proposes to revise the definition of generic drug to include approved follow-on biologic products for purposes of non-LIS catastrophic and LIS cost-sharing.

Cleveland Clinic Comment:
While we appreciate the Agency's intent for the proposed inclusion of follow-on biologic products, or biosimilars, in the definition of generic drug, Cleveland Clinic has serious reservations about this proposal.

Biologic drug products are dramatically more expensive than their small molecule counterparts, in large part because they are highlight targeted, treat small patient populations (often by way of specialty diagnostics or genomic profiling), and are extremely expensive to manufacture. The Agency's rationale for the proposal is to provide an incentive for low-income Part D beneficiaries to choose a more affordable option that can safely meet their needs. Moreover, CMS bears a significant burden of the cost for these drugs particularly in the catastrophic portion of the Part D benefit. Classifying biologics as generics would ostensibly reduce the Agency's cost burden.

CMS states it would limit this proposed modified definition of generic drug to specific beneficiary categories in order to avoid any misperception of treating biosimilars as generic drugs in all situations. However, defining generic drugs to include biosimilars, even within a narrow purpose, could have the unintended effect of creating a broader false equivalency in the industry. This would conflict directly with FDA policy, which distinguishes generic drugs from biosimilars. More importantly,

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because of the highly variable and targeted nature of biologic drugs, serious implications for patient safety and clinical effectiveness arise if biosimilars are treated like generics. They are, to use a phrase, not "apples to apples."

We also note that there are occasions when pharmacies negotiate with reference drug manufacturers on pricing that could end up lower than that for a generic drug, generating savings for the beneficiary and CMS. We do not believe this proposal to classify biosimilars as generic drugs is the right one. CMS should consider an alternative approach to increase Part D enrollees' access to more affordable biosimilars.

Request for Information Regarding the Application of Manufacturer Rebates and Pharmacy Price Concessions to Drug Prices at the Point of Sale

***CMS Request*:**
CMS seeks public comment on how to "most effectively design a policy requiring Part D sponsors to pass through at the point of sale a share of the manufacturer rebates they receive, in order to mitigate the effects of the DIR [Direct and Indirect Remuneration] construct on costs to both beneficiaries and Medicare, competition, and efficiency under Part D."

***Cleveland Clinic Comment*:**
As providers of health care, Cleveland Clinic is primarily concerned with the health and wellness of its patients in Northeast Ohio and beyond. As the cost of life-saving prescription drugs has risen for Medicare beneficiaries, the ability of Cleveland Clinic clinicians to care for patients falls into jeopardy; if patients cannot afford the drugs our clinicians prescribe, our hands become tied. As such, our interest is in making prescription medicines as accessible and affordable as possible to Medicare beneficiaries.

The changes proposed by CMS therefore present a conundrum – lower the cost of drugs at the point of sale, therefore lessening the burden of co-pays on frequent purchasers of drugs; or leave the current system in place to preserve downward pressure on premiums that DIR creates. In either case, Medicare beneficiaries face more money out of pocket.

In an ideal scenario, beneficiaries would not be presented with either option. The route of the growing out of pocket costs are the growing costs of prescription drugs. Whatever the cause of that increase may be – those costs are being felt by Medicare beneficiaries across the country.

Recognizing that issue is not up for comment, Cleveland Clinic supports the application of reductions in the POS price that would ease the burden on frequent purchasers of prescription drugs. While CMS has not released data to this point, we suspect that a small number of Medicare Part D beneficiaries are responsible for a significant number of the drug purchases. As such, that smaller group would experience a more meaningful reduction in price than all Medicare Part D enrollees would experience from a lower premium.

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Thank you for conducting a thoughtful process that allows us to provide input on such important issues and for your consideration of this information. Should you need any further information, please don't hesitate to contact me.

Sincerely,

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