Medicare Advocacy Recovery Coalition

January 16, 2018

BY ELECTRONIC DELIVERY
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Seema Verma, M.P.H. Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Re: CMS-4182-P: 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

Dear Administrator Verma:

The Medicare Advocacy Recovery Coalition (MARC) thanks you for the opportunity to comment on the proposed rule entitled 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 (CMS-4182-P; RIN 0938-AT08), 82 Fed. Reg. 56336 (November 28, 2017) ("the Proposed Rule"), and particularly on the Medicare Prescription Drug Benefit (or Part D) proposals to implement the Comprehensive Addiction and Recovery Act (CARA) law. We applaud the Agency's initiatives to address the opioid crisis across our country, and to ensure that frequently abused drugs are appropriately managed so that Medicare beneficiaries at risk of abuse and addiction cannot access them through the Part D program.

We write today to urge CMS in both its final rule and in the final rule preamble to address how frequently abused drugs could be accessed through Workers Compensation Medicare Set Aside arrangements (MSAs). As CMS is aware, during the MSA process CMS reviews Medicare Secondary Payer proposals for future care, and advises beneficiaries on proposed plans of care. Unfortunately, at a time when the entire federal government is working to curb opioid use, CMS in the MSA process is inadvertently suggesting use be expanded.

More specifically, following the submission of MSAs to CMS by beneficiaries or those funding beneficiary care, the Agency often proposes back modifications to care plans. In many cases a beneficiary may need some pain medications, such as an opioid– which if used beyond their medically necessary requirements can lead to addiction and other abuse. Unfortunately, the routine and consistent practice of CMS is to require MSA payment for *lifetime* use of highly potent and frequently abused drugs. These CMS recommendations are far beyond any evidenced-based guideline recommendations, and could cause harm to the beneficiaries involved if they misconstrue the CMS recommendations as federally sanctioned treatment guidelines or requirements.

Although CMS has repeatedly been advised of the issue, to date the Agency has taken no action to remedy the inappropriate recommendations in its MSA process other than to state that the Agency itself does not view the MSA as a treatment requirement or guideline. Whether or not true, that does not change the fact that beneficiaries might misconstrue the Agency recommendations as treatment requirements, which alone is reason for CMS to amend its regulations and ensure, as part of CARA implementation, that it will no longer include in MSAs long term utilization of frequently abused drugs.

There is a second reason to address this issue through this rulemaking. Frequently abused drugs are included in MSAs because if not paid for through an MSA they would be paid for through a Part D Plan. Thus, the proposed Part D rule is an ideal and important forum through which to address the use of opioids and other frequently abused drugs in MSAs.

Given the intersection of the Part D program and MSAs, MARC specifically asks that CMS clarify in its preamble to the Final Rule that it will adopt the same maximum opioid standards in MSAs that it uses for evaluation of prescription drug plans and Medicare beneficiaries in the Part D program. More specifically, CMS in 2018 has implemented (through policy) a 50 morphine milligram equivalent (MME) standard referenced in the Center for Disease Control (CDC) Guideline for Prescribing Opioids for Chronic Pain (CDC Guidelines, March 2016) as the threshold to identify beneficiaries who appear to be at high risk due to their opioid use. 82 Fed. Reg. at 56342. We encourage CMS to adopt this standard in its final rule, and to clarify in the preamble that it will use the same standard as the maximum amount of frequently abused drugs that should be included in any MSA. Given that once adopted the 50 MME standard will be the maximum amount of opioid (or other pain medication) that a beneficiary would be allowed to obtain through the Part D program, the same limit that should be used in MSAs.

We appreciate that MSAs are voluntary arrangements which project the future costs of care. If the proposed rule is finalized, Part D utilization of frequently abused drugs will be curtailed in the future. Given that MSAs are intended to account for only those amounts otherwise payable by Medicare (in this case, the Part D program), the same utilization limits should be adopted. Moreover, no branch of the federal government should be issuing documents, even inadvertently, which could be viewed as recommending lifetime use of painkillers. We ask that the Final Rule preamble address the treatment limits for frequently abused drugs and clarify that those limits will also apply to MSAs.

We thank you for consideration of these comments, and welcome any questions or follow up that you may have. Please feel free to contact me at (571) 239-1476 or susan@murdockinc.com if we can provide any additional information.

Sincerely,

Greg McKenna, Chair
Medicare Advocacy Recovery Coalition (MARC)