Crystal Carter

From: Amy Bilton <aeb@nbkllaw.com>
Sent: Monday, December 18, 2017 5:40 PM
To: sherri.mcqueen@cms.hhs.gov; seema.verma@cms.hhs.gov
Cc: McNabb, Brian (Cassidy) (Brian_McNabb@cassidy.senate.gov); Lucas, Jeff (Cassidy) (Jeff_Lucas@cassidy.senate.gov); Jill Dulich (Jill.Dulich@NatCouncil.com); 'Gary Patureau'; amanda.burd@cms.hhs.gov
Subject: Follow-up: Opioids in the WCMSA

Dear Ms. McQueen,

Thank you for taking the time to speak with us last week concerning how CMS currently forecasts future prescription drug recommendations in the WCMSA for beneficiaries with long-term opioid usage in their claim history. We look forward to working with CMS to address the above concerns, to do our part to bring "all hands on deck" in minimizing (or even eliminating) the WCMSA's role in perpetuating the opioid epidemic in our country. The National Council of Self Insurers joins NAMSAP in our concerns about how opioids are currently handled by the WCRC in WCMSAs. CMS' current policy: does not follow evidence-based medicine or guidelines; effectively sanctions and endorses the harmful, long-term opioid use by the beneficiary; and needs to be changed.

We first mentioned concern that the recommendations section of the WCMSA approval letter includes an itemization of medications, including opioids, that are projected at the same dosage and frequency as has been filled in the six to twelve months before submission, over the full life expectancy of the beneficiary. While this may not ultimately be what the beneficiary uses the WCMSA funds for, the recommendations section sends the wrong message to the beneficiary about the efficacy and safe duration of opioid usage without acknowledging the high likelihood of misuse and abuse when taken chronically.

Second, we expressed concern that the WCMSA includes monies that overfund the anticipated future medical needs of the beneficiary. The opioids in particular are priced, as mentioned above, in doses never meant to be taken over life expectancy. In our experience, 80% of WCMSAs are overfunded, and many of those never touched, which lends support to this position.

Third, the WCMSA monies are given to the beneficiary directly, with no gatekeeper to oversee the post-settlement opioid usage. Beneficiaries taking long-term opioids, many in excess of a 40 milligram daily Morphine equivalent doses (MEDs), are given tens to hundreds of thousands of dollars without any of the safeguards which would occur if Medicare or Part D providers were coordinating the benefits, including drug utilization review and red flags for both high MED usage and obtaining prescriptions from multiple prescribers.

There are, of course, serious and grave public health considerations stemming from each of our concerns.

You requested a list of options from NAMSAP to address what we see as the institutionalizing of opioid misuse and abuse within the context of the WCMSA. Here are some of our thoughts:

Evidence Based-Medicine: CMS can begin with the already-existing Reference Guide as a basis to bring evidence-based guidelines to the recommended WMCSA allocations in cases involving opioids, specifically by using the CDC guidelines.

- NAMSAP proposes following the CDC guidelines for tapering every beneficiary from long-term opioids at a rate of 10% per week until fully weaned.
- An exception may be made for terminal patients and those with malignancy.
- Such a recommendation would also serve the benefit of reducing the chances of dangerous and possibly lethal polypharmacy combinations with other medications such as benzodiazepines, sedatives and muscle relaxants.

- We also recommend that WMCSAs involving beneficiaries who have demonstrated negative Urinary Drug Screens (UDS) within the last six months have a zero opioid MSA allocation recommendation to prevent the likelihood of diversion and the risks associated therewith.

Post-operative allocation recommendation: NAMSAP acknowledges that short-term opioids may be safely used post-operatively short-term.

- Post-operative allocations of opioids would be acceptable for 3-5 days.
- No more than five days of post-operative opioids should be considered in the allocation given the most recent findings from the CDC.

State law: With all this noted, allocation recommendations should acknowledge individual state law maximums that may limit opioids even further (e.g. 7-day maximum for opioid prescriptions in Louisiana, 5 day maximum in Ohio, etc.), and also limit the primary responsibility of the primary payer.

We also wanted to address your concerns about the Division's perceived lack of statutory and regulatory authority to prepare WCMSA allocations that do not directly extrapolate over life expectancy the same medication dosage and frequency as has been filled over the past 6-24 months. The Comprehensive Addiction and Recovery Act of 2016 ("CARA") gave Medicare programs the authority to limit the beneficiary's access to coverage for frequently abused drugs such as opioids simply upon: identification of high-risk behaviors; and with issuance of notice. In acting on CARA, CMS' own 2019 proposed rules for PDPs codify CMS' current drug utilization review (DUR) programs, which CMS pointed out led to a 61 percent decrease in very high risk opioid overutilizers from 2011 to 2016. Thus, there is clearly statutory and regulatory authority for taking the same types of actions NAMSAP proposes.

We hope the above possible solutions are helpful and provide food for thought. We truly hope we can work together to bring patient safety in balance with protecting the Medicare Trust Fund.

We look forward to CMS' written response, and the continued dialogue.

Gary Patureau and Amy E. Bilton
Co-chairs, Evidence-Based Medicine Committee
National Alliance of Medicare Set-Aside Professionals