March 5, 2018

Unhelpful and Risky:
Health Professionals' Response to the 2019 Notice of Methodological Changes for Calendar Year 2019 for Medicare Advantage Capitation Rates, Part C and D Payment Policies and 2019 Draft Call Letter, CMS 2017-0163

We write as medical, addiction, pain and rehabilitation professionals to oppose the CMS 2019 proposed policy for 2019 that would impose denial of payment at point of sale for two types of prescription (1):

· Prescriptions for any beneficiary where cumulative opioid dose total exceeds calculated total of 90 morphine milligram equivalents (MME), subject to appeal
· Prescriptions of 7 days or greater for "opioid naïve" patients without exception or variation for any human circumstance including cancer, hospice, suspected deadly disease, or major geographic barriers

This policy will affect up to 1.6 million Medicare beneficiaries who received >120 MME for at least one day (per the Proposal), and far more than the 500,000 chronically dosed at >120 MME for at least 3 months, according to the HHS Office of the Inspector General (2).

Upfront, we assert that excess opioid prescribing over the last 15 years was adverse and required correction. Signatories to this letter include professionals who assisted the 2016 CDC Guideline (3), editors of scholarly journals, individuals who have set up systems of care to remediate adverse prescribing, as well as experts in pain, addiction & primary care.

Our objections to the payer-imposed 90 MME proposal are four-fold:

1) It will accelerate non-patient-centered, nonconsensual opioid dose reductions.
While a strong case can be made for consensual, supported opioid dose reductions for voluntary patients, no data support nonconsensual/forcible dose reductions or curtailment in otherwise stable patients that have become common as prescribers react to regulations, mandates, insurers and fear for professional security (4). There is anecdotal evidence of harm (emotional trauma, medical or psychiatric deterioration, suicide, (5-8)) that we believe the CMS proposal will accelerate, despite an appeal mechanism whose flaws will be noted below.

2) The policy does not agree with the 2016 CDC Guideline on Prescribing Opioids (3).
The dose thresholds featured in the Guideline's statement pertain specifically to dose escalation from a dose below to a dose beyond the threshold (Recommendation 5). The Guideline does not recommend that these thresholds be used as targets for non-consensual dose reduction for patients who are already prescribed a higher dose of opioids (Recommendation 7). A calibrated

evaluation of harm and benefit should guide care. The CMS proposal numbers among many initiatives that impede the 7th Recommendation.

3) The proposal does not consider adverse impacts on pharmacies, physicians or patients in the context of multiple regulatory initiatives, and it will accelerate patient abandonment (9).

The appeal mechanism proposed by CMS calls for payers to accept a simple attestation that a higher dose is "medically necessary". The bureaucratic work to affirm these attestations entails 3 and 4-way communication between pharmacy, Prior Authorization management contractors (e.g. Magellan), doctors' offices and insurers. The labor is substantial and uncompensated. Worse, the CMS proposal does not in any way provide the targeted case management for truly high-risk patients that was recommended by the OIG. The CMS plan risks accelerating a chaotic pattern of churn, abandonment and medical harm to patients who receive opioids as physicians flee an increasingly risk-laden and cumbersome decision matrix that may not advance patient safety.

4) **The proposal does not include metrics to evaluate how it affects patient health or access to care.**

The plan avows no metric for success other than reducing certain measures of prescribing. Neither patient access to care nor patient health outcomes are mentioned. Where patients receiving opioids are redirected to pain specialists for opioid management, access to such specialists is limited and there are anecdotal reports of invasive procedures being required as precondition for continued opioid receipt. These procedures involve risk and cost. Thus far, a 48% reduction in high dose prescribing since 2010 (10) has not been accompanied by a reduction in the number of deaths ascribed to natural or semisynthetic opioids (absent heroin or fentanyl) since 2011 (9300-9800 yearly according the National Vital Statistics System (NVSS). A focus on prescription reduction, absent patient outcome assessment, is inadequate.

Regarding the 7-day limit, signatories agree that on whole, shorter prescriptions are prudent in most situations. They are likely to reduce risk of diversion. However, regulations on this matter have proceeded in many states already (9). The CMS plan allows no exceptions even for patients with suspected metastatic cancer, or hospice, and merits reconsideration.

References follow below signatures. Signatures are indicated with ***C*** to indicate a formal role in developing/reviewing ***the CDC Guideline***, **A** for addiction expertise, ***P for pain, PC for primary care***. Views here are those of the authors alone, and **do not represent positions of their employing organizations**, federal or otherwise. Signature reflects consent for public posting of our names as well.

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