June 14, 2018

Comments on the Note to Medicare Advantage Organizations, Prescription Drug Plan Sponsors, and Other Interested Parties: Subject – Advance notice of Methodological Changes for Calendar Year 2019… Part 1 issued December 27, 2017, Part 2 issued February 1, 2018 – at <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Announcements-and-Documents.html>

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We appreciate this opportunity to comment on important aspects of this Note. I lead a program dedicated to making it possible for frail and disabled persons in their last years of life to live as comfortably and meaningfully as possible, at a cost that is sustainable for families and for the society. We work in the public interest; indeed, our main reform agenda is to engender a monitoring and management function for communities, so that local entities can have a hand in ensuring good care for their elderly residents, a reform called MediCaring Communities (<https://medicaring.org/book> ).

**Quality Measures.** This Note conveys a remarkable notice of improved quality measures for persons living with the serious disabilities and illnesses associated with advanced old age or with advanced illness at a younger age. Many of these are being developed by NCQA, and we would especially encourage development, testing and inclusion of measures of functional status as an arbiter of exclusion from some current quality measures. Consider that a person who is only 67 years old but who has Alzheimer’s dementia and 2 or more ADL dependencies should not be getting a mammogram or tight control of diabetes or hypertension. Measuring functional status and having it available in the data set would allow more appropriate exclusions than are currently possible, since current exclusions are almost entirely age-related. This is explicitly considered as a cross-cutting exclusion for advanced illness (p. 146), which we support. We also enthusiastically endorse the initiatives to start measuring substance abuse, polypharmacy, CNS and ACH polypharmacy, and care planning (Part 2, p. 149+). The idea of changing the readmission measure to measure readmissions for a population (Part 2, p. 145) will require some testing of adjustments needed, but it is a much more appropriate metric than the hospital-specific readmissions/discharges metrics now in common use.

CMS proposes to add three medication adherence measures to the Star Ratings Program (diabetes, hypertension, and cholesterol) (Part 2, p. 123) and to adjust them on the basis of socio-demographic factors. CMS should certainly take this opportunity to begin to exclude patients with advanced illnesses. At present, this would be limited to certain diagnoses, a few indicators of advanced illness (e.g., oxygen for COPD, feeding tubes, nursing home residence) and also hospice enrollment, but soon the exclusion could also turn on an algorithm that reflected diminished cognitive and/or physical function associated with age or diagnoses and drawn from the data required under the IMPACT act.

**Risk Adjustment**. (Part 1) We contend that CMS should include HCCs 51 (Dementia with complications) and 52 (Dementia without complications) in the additional HCCs that are being added to the new HCC model for MA plans. These two HCCs represent clinically meaningful,  prevalent, costly conditions in the Medicare population that are not discretionary diagnoses, meeting the criteria established for including new HCCs into the model. In addition, they are already in the model for ESRD. It is not at all clear why such an important set of diagnoses are not in the HCC model for MA plans generally.  In the current V21 model, which was the original proposed revision to the V12 HCC model, the HCC weights for 51 and 52 are significant. With the growth in programs that focus on high need Medicare beneficiaries, and the increased prevalence of dementia among those groups, it is perplexing that CMS would exclude such a costly and prevalent condition from risk adjustment. The exclusion requires CMS to distort other types of targeting criteria (such as the definition of Tier V in CPC Plus). Since the model was estimated in 2009, a number of factors, such as the expansion of LTSS services, may have altered the relationships of costs and conditions to Medicare, where there is substitution between Medicaid (through LTSS) and Medicare funded services.

Going forward, it would be better for CMS, the primary payer for health care services for the elderly, to have a risk adjustment model that includes dementia, which is one of the more costly and prevalent conditions in the elderly population. Correcting this omission would be a useful product from the proposed effort to re-estimate the HCC model.  The evaluation CMS indicated it will produce by December 2018 should explicitly evaluate the performance of the current models in patients with cognitive Impairment, and if performance is similar to their prior evaluation of risk adjustment in patients with Cognitive Impairment (with a predictive ratio of .86), CMS should describe why explicitly including HCCs 51 and 52 would not improve risk adjustment.

MedPAC has recommended that Medicare use a 2-year look-back for chronic conditions in estimating the HCC, since some important diagnoses do not show up in the most recent year but still are very important. A person who has established COPD and could have a year marked by a fall with injury and a medication-related adverse event, neither of which happened to carry forward the COPD diagnosis. The person still has COPD, and the evidence is that a 2-year look-back makes the model more reliable and accurate.

CMS should also recalibrate the HCC model for PACE. Once the HCC model is recalibrated, CMS should re-compute the frailty adjustment for PACE. The current model is a decade old, and much has changed. Just as the ESRD model needed recalibrated, so does the PACE model, aiming to have it more closely estimate likely costs.

**Patient Contribution to Medicaid LTSS**. The Note offers technical assistance for D-SNPs pursuing Managed LTSS and expanding their Model of Care (Part 2, p. 189). It would be important to expand that technical assistance to enable states to include persons needing LTSS but who have only a small amount of income over the state’s Medicaid eligibility limit. Some states already provide a calculation of a patient pay amount for persons in a home-based nursing home diversion program. Since a very large number of frail and disabled elders have incomes just a little above Medicaid eligibility, which is not enough to purchase the supportive services that they need, having a way to get Medicaid supportive services without entering a nursing home is a very strong policy strategy. However, the complexity of establishing the patient pay amount requires some technical assistance, perhaps mostly drawn from the states that already manage this endeavor.

**HRA to Add Functional Status to Claim Stream.** The Note allows a Rewards and Incentive Program that includes a Health Risk Assessment, which is a very important component of comprehensive care for elders (Part 2, p. 186). CMS should develop a way in which an HRA regularly includes at least a test of cognitive function and a test of ADL function, and then the results should be able to be detected in the claim stream so as to be combined with the assessments in post-hospital care under IMPACT.

**Health-Related Services.** The Note allows new flexibility in enabling MA plans to pay for health-related non-medical services, so long as they offer these to all of their beneficiaries similarly situated. This change in CMS regulations could be a very important direction to correct, at least partially, the inattention to supportive services in the U.S. To that end, it is important that the Note (and the NPRM before it) do not define the scope of possible services to be allowed, beyond requiring that they be available uniformly (Part 2, p. 184) and be health-related. All of the examples in the Note and in the NPRM relate to medical diagnoses. CMS should make clear that services availability can turn on disability (e.g., 2+ ADL dependencies) or the combination of disability and informal social support (so that a person living with disabilities who has no volunteer help would qualify for services such as home-delivered meals, whereas a person with the same diagnoses and disabilities who has a live-in caregiver would not be considered to be similarly situated). In the same vein, the array of services needing buttressed should extend to nutrition of this sort, along with housing modifications and other supportive services. These can be “diagnosed by a plan provider” (Part 2, p. 184), but this will be much more a functional status and a parallel need for a supportive service, rather than a conventional medical diagnosis. It is a good feature that the flexibility to pay for some non-medical health-related supportive services can be initiated in counties, rather than being required to cover the MA plan’s whole territory at the start. CMS should aggressively examine how MA plans are using this new flexibility and should share the insights gained quickly.

**Opioid Policies.** Hospice and cancer patients being excluded from most proposed policies is a generally appropriate start, but this is still a very imperfect dividing line. People with COPD may need morphine at bedtime to get some sleep. People with some destructive arthritis syndromes live tortured lives without opioids. And, of course, persons living with advanced illnesses often need more aggressive treatment of pain than is yet commonplace. The logistical issues of coping with 7-day supplies are quite severe. It seems that the exceptions process has to be accomplished in much less than 7 days, or the patient will end up with a very uncomfortable gap in care. Even requiring direct signatures can lead to bizarre combinations of transportation and mistrust. CMS needs to be very careful about assigning responsibilities to pharmacists, since there is no evidence that pharmacists are better able to manage opioids than physicians, who are clearly often inadequately prepared. People with gaps in opioids will sometimes have to seek street drugs, with their obvious problems, or they may “choose” to exercise the option of physician-aid in death (deliberate overdose to be dead).

In short, the policies proposed here are certain to be inadequate, both to stem the opioid overuse and to assure appropriate use. The nation needs to reassess the overall approach to therapeutic use, diversion, and abuse. Most likely, legitimate use needs to be monitored with Prescription Drug Monitoring Programs (PDMP) and, except for short-term use in persons having surgery (or another acute injury) or nearing death, opioid prescribing should probably be brought under the control of a manageable number of pain treatment centers. These expert centers would have multi-disciplinary teams and monitors of performance, and would relate to local providers through various communication devices (e.g., Project ECHO). So, the person needing pain management would have the plan of care and any contract needed set at the pain treatment center, but the local physician (or NP/PA) would do the actual prescribing and monitoring with the PDMP keeping track of the patterns of the centers and one or more contractors providing technical assistance.

The current policy proposals may be all that CMS can do now, but CMS and other federal agencies should be enabling some states or regions to take some more innovative approaches and thereby to learn what more fundamental reforms might achieve, at what cost in suffering and in costs.