



# CY 2017 Advance Notice and Draft Call Letter Summary of Provisions and Impacts



The Centers for Medicare and Medicaid Services (CMS) released its Advance Notice of Methodological Changes for Calendar Year (CY) 2017 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2017 Draft Call Letter on February 19, 2016.

The purpose of the Advance Notice and draft Call Letter is to notify Medicare Advantage Organizations (MAO) and Part D sponsors of proposed changes to the Part C and Part D programs for the following plan year, including but not limited to:

- Planned changes in the MA capitation rate methodology and risk adjustment methodology applied under Part C for CY 2017

- Proposed changes in the Part D payment methodology for CY 2017
- Potential changes to the Part C and Part D programs that MAOs and Part D sponsors should consider while preparing their 2017 bids
- Policy changes designed to improve the overall management of the Medicare Advantage and Prescription Drug programs

The changes contained in the Advance Notice and draft 2017 Call Letter are to be effective for the 2017 contract year. The final version of the Advance Notice and Call Letter will be released on April 4, 2016.

## Our Perspective

As in previous years, CMS proposed a number of significant payment and policy changes in the Advance Notice and Call Letter.

Many of the proposed changes will have a direct impact on MAO reimbursement for 2017 and beyond. For instance, CMS published larger than expected Fee-For-Service (FFS) growth percentage and the CMS-HCC model will experience major changes as the model shifts to a new six-segment community model. Additionally, CMS intends to adjust the weights assigned to the risk scores from the Risk Adjustment Processing System (RAPS) and Encounter Data System (EDS) by weighting them each equally at 50%.

New adjustments to the Star Ratings program should increase the ratings for contracts with higher proportions of Low Income Subsidy/Dual Eligible (LIS/DE) and disabled beneficiaries and eliminate the perceived penalty for sponsors with proportionally higher LIS/DE populations.

Significant emphasis continues to be placed on Part D sponsors' failure to comply with CMS' adjudication requirements for coverage determinations and redeterminations, which result in auto-forwards to the Independent Review Entity (IRE). Because the volume of cases auto-forwarded to the IRE remains significant and sustained, CMS proposes to increase the severity of enforcement actions in this area. Additionally, findings from the one-third financial audits will also now be subject to potential enforcement action.

CMS also continues to review and refine leading practices for provider directories, its overutilization monitoring programs, and Medication Therapy Management (MTM) program processes.

One noted exclusion from the notice was additional guidance on home visits for the purpose of risk adjustment. New guidance around home visits was expected by the industry and this noted absence means existing processes and policies remain unchanged for 2017. There were also no new proposed restrictions on the use of preferred cost sharing pharmacies.

## Attachments I-V: CY 2016 Advance Notice

For CY 2017, CMS published FFS growth percentages approximately 1% greater than their preliminary estimates released earlier this year. This indicates that MA benchmarks will increase greater than initially expected. Other adjustments were consistent with prior CMS communications including the change in the statutory minimum coding adjustment factor and the CMS-HCC model to a six-segment community model in order to treat fully dual eligible members more fairly in relation to their expected costs.

For the first time, CMS has addressed potential overpayments to Employer Group Waiver Plans (EGWP) by indicating that they are proposing that EGWP sponsors will no longer submit MA bids and that their payments will be based on the average bid of individual sponsors, despite MedPAC previously noting this as a concern.

Lastly, CMS has moved to increase the submission weight of Encounter Data System (EDS) submissions to be 50% and RAPS submission to be 50%. This is a large increase from the previous weight of 90% on RAPS submission and 10% on EDS submissions.

Overall, the combined adjustments are expected to result in rates increasing by approximately 1.5% to 2.0% on average depending on the impact of the CMS-HCC changes. Further, the actual impact will differ depending on the percentage of Fully-Integrated Dual-Eligible (FIDE) a sponsor has due to the CMS-HCC model changes which should increase the FIDE rates by approximately 9% to 10% prior to accounting for any other changes.

## Moratorium on Insurer Fee

A one-year moratorium of the Annual Fee on Health Insurance Providers, originally established as part of the Affordable Care Act, will go into effect for 2017, per Title II, § 201 of the Consolidated Appropriations Act of 2016. This moratorium represents a reduction of approximately 2% for the organizations that were required to pay the fee for 2016. Sponsors should account for this moratorium in their 2017 bids submissions through lower bids, higher rebates, or additional supplemental benefits.

### MA Growth Percentage

The current estimate of the change in the national per capita MA growth percentage for aged and disabled enrollees combined in CY 2017 is 2.92%. This estimate reflects an underlying trend change for CY 2017 in per capita cost of 2.68%.

For CY 2017, all counties will be fully transitioned to the new rate methodology. Additionally, all MA county rates are now based on the specified amount (100 percent of the 2017 FFS rate, estimated as described herein). The county FFS rates will be rebased for 2017 and CMS proposes to update claims data to ensure use of the most recent FFS schedules and payment rules.

### FFS Growth Percentage

The current estimate of the change in the national FFS MA growth percentage for aged and disabled Non-ESRD is 3.06%. This growth percentage represents the change in cost relative to the 2016 FFS non-ESRD PMPM estimate in 2015 to the 2017 non-ESRD PMPM estimate in 2016.

Since all counties in 2016 will be fully transitioned to the new rate methodology, this trend is representative of the expected increase in the benchmark if all other factors were held equal.

### ACA Regulation Impacts

The impact of transitioning to the new methodology as well as changes to the quartile percentages will result in a reduction of revenue of 0.5% on average. It should be noted that the actual impact will vary by county since most counties have already fully transitioned to the new methodology and many counties have not changed quartile bands.

### Coding Adjustment Factor

Each year, CMS implements an across-the-board adjustment to offset the effects of higher levels of coding intensity in MA. For 2017, CMS proposes to update the MA coding adjustment factor to the statutory minimum of 5.66%. This is an increase from 5.41% for CY 2016, representing a potential payment decrease of 0.25%. CMS also stated that they intend to continue monitoring coding intensity

and utilize their authority to increase the offset as appropriate.

### FFS Normalization Factor

In addition to the coding adjustment factor, each year CMS applies a normalization factor to adjust beneficiary risk scores so that the average risk score in FFS is held to 1.0 in subsequent years. The preliminary normalization factor for the CMS-HCC model implemented in 2017 is: 0.993. This is an increase from 0.992 for CY 2016, representing a potential payment decrease of 0.10%.

### CMS-HCC Model

In 2017, CMS proposes to implement an updated version of the CMS-HCC risk adjustment model that would include revisions to the community model that replace the single community segment with six separate model segments (non-dual aged, non-dual disabled, full benefit dual aged, full benefit dual disabled, partial benefit dual aged, partial benefit dual disabled). Each segment would have relative factors that are independently developed for that segment and would reflect the specific relative costs for an HCC for that subgroup. According to CMS, the impact of these changes will result in an average decrease in revenue of 0.6%, but based on the detailed information published it appears that the decrease may only be 0.1%. In a call with the industry on February 22, 2016, CMS commented that they will contemplate releasing additional information on how they estimated the 0.6% reduction.

### Employer Group Waiver Plans (EGWPs)

Under this proposed rule change, CMS will waive the bidding requirements for all MA employer/union-only group waiver plans.

In reviewing EGWP bids in recent years, CMS has found that while employer group bids are higher than individual market MA sponsors, the average projected risk scores for employer group members are lower than for individual market MA enrollees. CMS expects the bids for employer group sponsors to be lower if projected costs are lower. As a result of this difference, the average rebate (which is a percentage of the difference between the sponsor's

bid and their benchmark) is significantly higher for individual market sponsors than for employer group sponsors.

Removing the administrative burden of submitting EGWP bids should facilitate additional offerings of EGWP sponsors to employer groups and unions. Furthermore, CMS is concerned about the competitiveness of employer group bids, as some sponsors do not compete in the open market and exclusively serve as sponsors to employer groups and unions.

As a condition of the bidding requirement waiver, CMS is proposing an alternate payment policy for EGWPs which will use individual market non-EGWP sponsor bids, including Regional Preferred Provider Organizations (RPPOs), submitted for 2017 to establish Part C county level payment amounts. Based on the information published by CMS, should EGWPs no longer be able to bid, EGWP revenue would be reduced by 3% to 4% on average, after accounting for rebate impacts, in relation to current CMS subsidies, but the overall change will vary by county and health plan.

One potential impact of this change is EGWPs will no longer be able to buy down the Part B premium using their rebate dollars. However, CMS has indicated that few EGWPs offer this as an additional benefit.

#### **RAPS and Encounter Data Blend**

In 2016, CMS initiated the transition to Encounter Data based risk scores by blending the risk scores, weighting the risk score from Risk Adjustment Processing System (RAPS) and FFS by 90% and the risk score from the Encounter Data System (EDS) and FFS by 10%.

For 2017, CMS proposes to shift the blend further to 50/50 by weighting the risk score from RAPS and FFS by 50% and weighting the risk score from the EDS and FFS by 50%. CMS believes this is the next step in the progression towards relying 100% on encounter data for plan-submitted diagnosis information.

#### **Puerto Rico**

Due to the unique circumstances in Puerto Rico, CMS has requested comments on how to improve the situation in Puerto Rico. CMS indicated that at this time they are not treating Puerto Rico any differently than any other counties and that they will use Puerto Rico experience to set the benchmarks. Nonetheless, CMS is aware of various concerns around Puerto Rico and they will continue to request industry support to try to identify issues that are present within Puerto Rico and a possible solution for handling such anomalies.

#### **Attachment VI: 2016 Draft Call Letter Section I – Parts C and D**

##### **Star Ratings Changes for 2017**

CMS is enhancing the Star Ratings program for CY 2017 to better align with stated policy goals. As part of those enhancements, CMS is not planning to add any new measures for 2017. However, CMS is proposing to change the rating methodology for several measures, including the following:

- Part C and Part D Improvement Measures – While the methodology remains the same as in prior years, the measure used for each improvement measure to account for measures will include at least two years of data
- Appeals Timeliness/Reviewing Appeals Decisions measures (Part C) and Appeals Upheld measure (Part D) – measure will include reopened cases that are decided by the Independent Review Entity (IRE) by May 1, 2016 instead of April 1, 2016
- Transition from ICD-9 to ICD-10 (Part C and D) – ICD-10 diagnosis codes will be included as they are incorporated by the measure stewards, such as the National Committee for Quality Assurance (NCQA) and the Pharmacy Quality Alliance (PQA)
- Appeals Upheld measure (Part D) – hospice appeal cases will no longer be excluded from this measure
- Medication Therapy Management (MTM) Program Completion Rate for Comprehensive Medication Reviews

(CMR) measure (Part D) – a detailed file during each HPMS sponsor preview period to list each contract's underlying denominator, numerator, and Data Validation score will be added since exclusions are applied to the sponsor-reported MTM data

In addition to the above modifications, the Improving Bladder Control (Part C) and High Risk Medication (Part D) measures are being proposed for removal. CMS intends to move these measures to the display page for 2017.

### Impact of Socio-economic and Disability Status on Star Ratings

In response to feedback and comments from a number of MA organizations and PDP sponsors concerning the potential impact of large percentages of Dual Eligible (DE) enrollees and/or enrollees who receive a Low Income Subsidy (LIS) on MA or Part D Star Ratings, CMS conducted a comprehensive study to determine if Star Ratings are sensitive to the Dual Eligible and Low Income Subsidy status of a sponsor's enrollees.

CMS research has provided scientific evidence that there exists a within-contract LIS/DE and disability effect for a subset of the Star Ratings measures. To counteract this effect, CMS considered two potential analytical adjustments to the Star Ratings Program:

- Categorical Adjustment Index (CAI) - A factor that would be added to or subtracted from a contract's Overall and/or Summary Star Rating to adjust for the average within-contract disparity which varies by a contract's proportion of DE/LIS and disabled beneficiaries
- Indirect Standardization (IS) – A measure-level adjustment which uses the ratio between a contract's actual (observed) and expected measure score, which is based on a contract's composition of LIS/DE and disabled beneficiaries using adjusted national means per selected measure

CMS conducted a simulation using the 2016 Star Ratings data to measure the change in the

distribution of ratings after applying the CAI and IS adjustments. CMS found that the CAI adjustments produced less movement in the Star Ratings, aligned better with the findings of their initial research, and tended to increase the ratings for contracts with higher proportions of LIS/DE and disabled beneficiaries, while the IS adjustments did not seem to do so as specifically and to the same degree. As a result of CMS' research, simulation results, and stakeholder comments, CMS is proposing to move forward with the CAI analytical adjustments beginning with the 2017 Star Ratings.

In addition to the larger CAI adjustment, CMS is also proposing two additional adjustments for sponsors solely serving beneficiaries in Puerto Rico:

- Use of an LIS indicator that would be used in conjunction with the analytical adjustment, which would be assigned to beneficiaries in Puerto Rico's contracts whose incomes would result in an LIS designation in the 50 states and DC (as Puerto Rican beneficiaries are not eligible for LIS)
- A reduction in the weights of the three Part D Medication Adherence measures to zero for the calculation of the Overall and Summary Ratings, while retaining the values and the associated weight of the three adherence measures for the calculation of the improvement factor

These adjustments should help better account for the proportion of Dual Eligible and low income beneficiaries in Puerto Rico.

### Potential Star Ratings Changes for 2018

CMS has proposed a number of potential Star Ratings changes for 2018 and beyond.

Among these changes is the potential addition of five new measures: Care Coordination (Part C), Depression Measures (Part C), Appropriate Pain Management (Part C), Use of Opioids from Multiple Providers or at High Dosage in Persons without Cancer (Part D), and Antipsychotic Use in Persons with Dementia (APD) (Part D). Of note for the proposed new measures, the Use of Opioids

measure is actually composed of three different opioid measures and will also be added to the patient safety reporting site, allowing CMS to collect additional data before adding these measures to the Star Ratings.

Several modifications to existing measures for 2018 are also being proposed, including changes to: Colorectal Cancer Screening (Part C Star Rating), Fall Risk Management (Part C Star Rating), Pneumococcal Vaccination Status for Older Adults (Part C Display), CAHPS measures (Part C and D), Medication Adherence for Hypertension (RAS Antagonists) (Part D Star Rating), MPF Price Accuracy (Part D Star Rating), and Drug-Drug Interactions (DDI) (Part D Display).

### **Program Audit Protocols**

Beginning with 2017 audits, CMS will release the next year's protocols in July 2016 as opposed to late fall.

This earlier release date will have an impact on two new audit protocols - Medication Therapy Management (MTM) and Provider Network Adequacy (PNA). CMS recognizes that in order to release audit protocols in July 2016, it will not have gathered enough information from the MTM and PNA pilot programs to implement these audit protocols for 2017; therefore, CMS will continue piloting these audit protocols in 2017 in an effort to gather enough feedback to facilitate any changes necessary.

### **Civil Money Penalty (CMP) Calculation Methodology**

A number of sponsors and industry groups have requested more information on the approach CMS uses to determine CMP amounts and how the impact of certain deficiencies are factored into a given CMP. CMS will release a memo describing its interpretation of the applicable rules in a CMP Methodology by 2017, but will allow for industry comment before finalizing the methodology.

### **Enforcement Action**

In 2017, CMS will continue to increase the level and severity of the compliance and enforcement actions imposed on sponsors that substantially fail to

comply with adjudication requirements for coverage determinations and redeterminations.

Data will be used to determine sponsors that are outliers with respect to untimely decisions and the corresponding rate at which cases are auto-forwarded to the Part D IRE. CMS has the authority to then impose CMPs against sponsors that substantially fail to comply with requirements related to coverage determinations, appeals, and grievances.

### **One-third Financial Audits**

Findings of noncompliance from one-third financial audits have identified significant financial errors, disallowed cost, and internal control weaknesses. While sponsors are required to put a corrective action in place to rectify their deficiencies, certain findings with adverse beneficiary impact warrant further enforcement action. Therefore, CMS will begin to consider the findings of noncompliance from the one-third financial audits for potential enforcement actions.

### **Attachment VI: 2016 Draft Call Letter Section II – Part C**

### **Provider Directories**

The importance of providing accurate provider directories to MA enrollees is emphasized for CY 2017. Preliminary data and continued stakeholder concerns have intensified the concerns of provider directory accuracy. Inaccuracy of directories impede access to care and bring into question the adequacy and validity of the MAO's network as a whole. The focus remains on ensuring provider directories are accurate for Medicare beneficiaries to facilitate informed decision-making regarding their health care choices.

Some MAOs are piloting the use of new technology to simplify the process of updating provider directories for physicians and other network participants. CMS has purposefully not prescribed the means by which MAOs must update their provider directories, to allow for innovation and encourages the use of technologies that provide data, including provider information on network participation, in a machine readable format.

Instances of non-compliance will be monitored through oversight methods by using contracted support that have developed a comprehensive process for monitoring provider directory accuracy. The data that is being collected will be used to drive additional reviews of network adequacy as well as future monitoring or audit-based activity. Therefore, sponsors should continue to implement periodic accuracy checks of provider directories through ongoing auditing and monitoring procedures.

In addition to increased oversight of provider directory accuracy, CMS is investigating ways to make provider directory requirements more uniform across CMS programs. Currently among MA, Qualified Health Plans (QHPs), and Medicaid managed care programs, MA provides the least prescriptive provider directory requirements. Regulatory updates would be needed to modify MA requirements regarding provider directories to better align with QHPs and Medicaid managed care programs which could include:

- Machine readable content
- Provider medical group
- Provider institutional affiliation
- Non-English languages spoken by provider
- Provider website address
- Accessibility for people with physical disabilities

#### **Total Beneficiary Cost (TBC)**

For 2017, the threshold will remain the same as in 2016 (\$32), however CMS will eliminate the coding intensity factor. CMS will also allow for some adjustments for organizations that receive quality bonus payments and adjustments greater than \$32 and, conversely, those that do not receive the quality bonus payments.

#### **Maximum Out-of-Pocket (MOOP)**

CMS will continue the current policy of affording MA sponsors greater flexibility in establishing Parts A and B cost sharing by adopting a lower voluntary

MOOP limit than is available to sponsors that adopt a higher, mandatory MOOP limit

However, the number of MA sponsors with voluntary MOOPs has decreased over the past several years which may call into question the value of allowing cost sharing flexibility and serve to minimize the impact of changes made to this policy. As a result, CMS intends to reduce or eliminate cost sharing flexibility in other service categories for voluntary MOOP sponsors, which would be accomplished over the next few years to minimize disruption to sponsors and enrollees.

#### **Alternative Payment Models (APM)**

In an effort to incentivize the transformation of the health care delivery system away from rewarding volume over value, CMS has set a goal to have 30 percent of Medicare fee-for-service payments made based on APMs by the end of 2016 and 50 percent by the end of 2018.

As a result, APM questions have been added to the Part C reporting requirements and MAOs would report on the proportion of payments made to providers based on categories of:

- Fee-for-service with no link to quality
- Fee-for-service with a link to quality
- Alternative payment models built on fee-for-service architecture
- Population based payment

To maintain consistency with HHS goals of increasing the proportion of payment made based on quality and value, CMS will continue to support MAOs efforts to improve cost efficiency, reduce costs, and improved health outcomes through the use of APMs.

#### **Attachment VI: 2016 Draft Call Letter Section III – Part D**

#### **Medication Therapy Management (MTM)**

Since MTM program submissions have increasingly high rates of initial approval, CMS is proposing to implement a modified annual MTM program review

process and add attestations to the HPMS submission model as described below:

- All Part D sponsors will continue to submit an MTM program description through HPMS each year. Sponsors will continue to submit change requests throughout the year
- Attestations of the Part D sponsor's compliance with Part D MTM program requirements will be added to the MTM submission module in HPMS
- Sponsors must attest to meeting the MTM program requirements during the annual submission. Sponsors must re-attest when they submit change requests. The user completing the MTM submission and attestations in HPMS must have the authority to attest on behalf of the organizations
- A subset of MTM program submissions will be comprehensively reviewed:
  - Any new contracts
  - Any contracts whose MTM submission failed initial review the prior year
  - Any contracts that failed reporting requirements data validation or audit for MTM (when implemented)
  - Any contracts that scored less than three Stars on the MTM comprehensive medication review completion rate measure
  - A random sample of other program submissions

CMS has also announced the Part D Enhanced MTM model, offering an opportunity for stand-alone basic Prescription Drug Plans (PDPs) in selected regions to offer innovative MTM programs, to improve quality of care while reducing costs. The Enhanced MTM Model test will begin January 1, 2017, with a five-year performance period.

The current MTM requirements are waived for the PBPs approved to participate in the Enhanced MTM Model and data on participating PBPs must not be reported per the Part D Reporting Requirements under the current MTM program. This MTM data will be reported in accordance with model terms and conditions. CMS will notify the subset of sponsors that are not subject to current MTM requirements.

Sponsors with contracts that include PBPs that are not eligible to participate in the model must ensure that those non-participating sponsors comply with all standard MTM program requirements, including the submission of MTM program details in HPMS.

### Clinical Decision-Making for Certain Coverage Determinations

Proposed changes would allow Part D sponsors to extend the timeframe to adjudicate certain coverage determination requests for drugs that require Prior Authorization or Step-Therapy. These coverage determinations would be limited to situations where a Part D sponsor is unable to obtain the required clinical information to make a determination and has made reasonable efforts to obtain the information and when the adjudication timeframe is affected by a weekend or a holiday.

CMS has observed, based on past experience, that, when the adjudication timeframe is affected by a weekend or holiday (or both), the plan sponsor may be less likely to reach a prescriber to obtain the necessary information before the adjudication timeframe expires. CMS is concerned that efforts to expedite a request may affect sound clinical decision-making and that denying coverage places the burden on the enrollee to request an appeal.

Should CMS submit a regulatory proposal to effect this change, the following principles would be considered:

- Extension timeframes in Part D would be shorter than MA (14 days)
- Extensions should only be granted when justified, in limited, non-routine circumstances and when in the best interest of the enrollee



- All extensions would require written enrollee notification
- It would not be appropriate for a Part D sponsor to utilize an extension for failure to conduct timely outreach

CMS has explicitly stated that this proposed rule change will not apply to exception requests (including exceptions to Prior Authorization and Step Therapy criteria).

As a result of this proposed change, Part D sponsors could see a decrease in program costs due to a perceived reduction in redeterminations that result from coverage determination denials based on lack of clinical information. Additionally, extension timeframes will most likely be adopted into CMS Part D audit protocols, requiring Part D sponsors to update CMS audit universe generation logic.

#### **Preferred Cost-Sharing Pharmacies (PCSP)**

Sponsors increased access to PCSPs dramatically for 2016. Therefore, CMS does not plan on making changes for 2017, specifically in regards to the outlier thresholds and will continue its PCSP policy as announced in the 2016 Call Letter and implemented for 2016 plan year.

For 2017, sponsors that provide PCSP pharmacy access within 2 miles to less than 40% of beneficiaries' residences in urban areas, within five miles to less than 87% of beneficiaries' residences in suburban areas, and within 15 miles to less than 70% of beneficiaries' residences in rural areas will be identified as outliers. Those that are identified as outliers will be required to disclose in marketing materials, including websites, that their sponsors' PCSP networks offer lower access.

#### **Part D Benefit Parameters for Non-Defined Standard Plans**

CMS has included additional tier models for CY 2017 with a non-preferred drug tier option in the CY 2017 Plan Benefit Package Software and Formulary Submission PRA information collection request. With the addition of a non-preferred drug tier, sponsors will have the option of selecting a non-preferred drug tier or non-preferred brand tier, but

not both. If sponsors continue to use a non-preferred brand tier, CMS will evaluate the brand/generic composition of that tier as part of the bid review process. Non-preferred brand tier outliers will be communicated for any sponsors that do not have a majority of brand drug products in that tier.

CMS is encouraging Part D sponsors to consider using a coinsurance for the non-preferred drug tier instead of a copay. A coinsurance (versus copay) structure will provide a more equivalent benefit to beneficiaries who use less expensive generic medications that are placed on a non-preferred drug tier. During the first year of implementation and until further notice, CMS will conduct an outlier test for those Part D sponsors who choose a copay for the non-preferred drug tier to determine if beneficiaries will receive a benefit for the majority of drugs on this tier at the proposed copay.

CMS also proposes to increase the specialty tier cost threshold from \$600 to \$670 by applying the annual percentage increase used in the Part D benefit parameter updates to the existing \$600 threshold.

#### **Drug Utilization Review Controls**

CMS has proposed multiple updates to the overutilization policy for Contract Year (CY) 2017:

- Due to a dramatic decrease in the annual number of APAP over utilizers since 2011, CMS has proposed to discontinue the report of APAP overutilization tickets in OMS beginning with April 2016. They will, however, continue to monitor APAP overuse
- As part of additional outreach to select Part D sponsors to review overutilization criteria and case management programs, CMS is proposing changes, and soliciting feedback, on their OMS Opioid Overutilization Methodology, to shorten the measurement period from 12 months to six months and use average morphine equivalent does (MED) rather than a count of 90 consecutive days of high MED

- Sponsors who adjudicate pharmacy claims at point-of-sale (POS) are expected to implement formulary-level cumulative MED POS edits effective January 1, 2017. Furthermore, to minimize claim rejections on false positives, CMS is proposing that sponsors implement both soft and hard cumulative MED POS edits, the specifications for which should be developed by the Pharmacy and Therapeutics (P&T) committees
- Sponsors should implement a soft formulary-level POS edit when an opioid prescription is presented following the initiation of buprenorphine addiction therapy. There will not be an overutilization monitoring system (OMS) measurement for concurrent use of opioids and buprenorphine, but CMS will continue to monitor utilization trends
- The Centers for Disease Control (CDC) is preparing a guideline for opioid prescribing to assist primary care providers in delivering safer, more effective chronic pain management for patients with pain outside of active cancer treatment, palliative care and end-of-life care

Sponsors must also implement adequate controls, such as rejected claims analysis, to validate that enrollees are receiving their subsequent extended days' supply on subsequent fills without interruption.

### Comments

The CMS comment period for this draft notice is open until 6:00 PM Eastern Standard Time on Friday, March 4, 2016.

If you would like to discuss any of the proposed payment or policy changes for 2017 with one of Deloitte's Government Programs leaders, please see the contact information on the following page.

### Extended Days' Supplies

Sponsors that offer a partial extended days' supply tier will be required to indicate within the plan benefit package (PBP) what specific drugs are not available as extended days' supply on the "Non-Extended Day Supply" HPMS supplemental file. CMS will provide additional training on this at a later date.

Additionally, in an effort to reduce potential prescription drug waste, sponsors will now have the option to allow an extended days' supply on all but the first fill. Should a sponsor choose to not allow for extended days on the first fill, the sponsor will need to indicate this at the tier level on their PBP. Sponsors may not require a follow up visit between the enrollee and his/her prescribing physician (step therapy) or a new prescription to receive the extended days' supply on the second fill. Sponsors will need to be cautious in developing their PBPs to make sure to not include such step therapy.

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