AMCP Academy of Managed Care Pharmacy® www.amcp.org

SUMMARY

AMCP Highlights: ***Advance Notice of Methodological Changes for Calendar Year (CY) 2019 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2019 Draft Call Letter***

Released: ***February 1, 2018***

Comments Due: ***March 5, 2018***

Earlier this evening the Centers for Medicare and Medicaid Services released the 2019 Draft Call Letter. Below is an initial summary of the highlights contained in the Draft Call Letter. AMCP will be working on a detailed summary that will be shared with AMCP members early next week.

Comments on this proposal must be submitted to CMS by March 5, 2018. AMCP will work with stakeholders to develop comments to CMS to ensure the perspective of managed care pharmacy is voiced as changes to payment policies and the Star Ratings are considered. You may provide feedback via email to Soumi Saha, Director of Pharmacy & Regulatory Affairs, at ssaha@amcp.org by Wednesday, February 28th on any of the provisions included in the Draft Call Letter. AMCP's final comments to CMS will be available on the AMCP website and also included in the Legislative-Regulatory Briefing Newsletter that is distributed to all AMCP members.

In addition, AMCP will host a webinar on February 27th from 2-3PM EST to review the proposed policy provisions and changes to Star Ratings that are applicable to AMCP members in the Draft Call Letter. This webinar is free for members and $69 for non-members. To register, please visit AMCP's Calendar of Events at http://www.amcp.org/Newsletter.aspx?id=23040.

The 2019 Final Call Letter is anticipated to be released on April 2, 2018.

New Strategies for Identifying Potential Opioid Abuse

CMS is proposing the following new strategies, which will work with the proposed codification of the current Opioid Monitoring System (OMS) under the Comprehensive Addiction and Recovery Act of 2015 (CARA):

- Identify beneficiaries that use "potentiator" drugs, such as gabapentin and pregabalin, in combination with prescription opioids (regardless of dose) for case management;
- Implement technical revisions to the Pharmacy Quality Alliance (PQA) measures used to evaluate plan sponsors' efforts to manage opioid abuse;
- Add the new PQA measure, Concurrent Use of Opioids and Benzodiazepines, to the Star Ratings system;
- Expect all plan sponsors to implement hard formulary-level cumulative opioid safety edits at point-of-sale (POS) at the pharmacy at 90 morphine milligram-equivalent, with a 7-day supply allowance;
- Implement a supply limit for initial fills of prescription opioids (e.g. 7 days) for the treatment of acute pain with or without a daily dose maximum; and
- Expect all sponsors to implement soft POS safety edits based on duplicative therapy of multiple long-acting opioids and request feedback on concurrent prescription opioid and benzodiazepine soft edits.

Definition of Health-Related Supplemental Benefits for Medicare Advantage Plans Could be Expanded

CMS is looking to expand the scope of the primarily health related supplemental benefit standard. Currently, an item or service defined as a supplemental health care benefit is not covered by Original Medicare, primarily health related, and

something for which the MA plan must incur a non-zero direct medical cost. Using a new interpretation, CMS states that for a service or item to be "primarily health related," it must diagnose, prevent, or treat an illness or injury, compensate for physician impairments, act to ameliorate the functional/psychological impact of injuries or health conditions, or reduce avoidable emergency and healthcare utilization. CMS believes this will give MA plans more flexibility in offering these supplemental benefits.

The call letter does state that the benefits offered under this broader interpretation must be medical appropriate and ordered by a licensed provider as part of a care plan if not directly provider by one. CMS says it will issue detailed guidance for MA organizations on this issue.

New Guidance for Part D Plan Sponsors on Coverage for Immunosuppressants Aim to Reduce Administrative Burdens
The Call Letter includes new guidance for Part D plan sponsors for performing due diligence when reviewing pharmacy claims for immunosuppressants. Immunosuppressants are one of several classes of drugs that are generally covered under Part D, but are covered under Part B when the patient has received an organ transplant paid for by Medicare. Sponsors have struggled with Part B/Part D coverage issues since the inception of the program; the new guidelines aim to resolve problems when Part D plan sponsors rely on prescribers for providing transplant coverage information.

- If the patient has no prior claims history with immunosuppressants, plans are expected to rely on information from CMS, or if the patient is covered under a Medicare Advantage plan, information from the patient's health claims. If the plan cannot access information from CMS, or from the patient's Medicare Advantage plan, the plan sponsor is expected to cover the prescription under Part D. The plan will no longer be required or expected to reach out to prescribers for additional information.
- If the patient has prior claims history for immunosuppressants, and CMS indicates that the patient received a transplant covered by Medicare, the plan must notify the patient that, going forward, their prescription will be covered under Part B. This is regardless of how the plan may have covered the prescription in the past.
- If the patient has prior claims history for immunosuppressants, and the plan does not have information from CMS or a MA plan regarding transplant coverage, but is made aware that Medicare covered the transplant during an audit, then going forward the plan will be required to cover the drugs under Part B, but no changes will be made to prior Part D claims.

Formulary Reference File to Drop Drugs Commonly Covered Under Part B and Drugs Rarely Covered Under Part D
CMS is proposing to stop including drugs that are typically covered under Part B, and drugs that, based on historical claims data, are rarely covered under Part D (but are not statutorily excluded) on the Formulary Reference File.

Agency Solicits Comments on Future Expansion of Over-the-Counter Coverage Policy, Mail Order Refill Consent
Currently, Part D plans are allowed to cover over-the-counter (OTC) drugs as part of a utilization management program that replaces a drug covered under Part D with the OTC drug. CMS notes that few plans offer OTC coverage and is requesting comments from stakeholders on ways that the agency could expand the benefit in the future to encourage broader coverage of OTC products when appropriate. Because there are no specific proposals included in the Call Letter, no changes will be made to 2019 policies for OTC coverage.

CMS is also soliciting comments on the current requirement that mail order pharmacies get consent from patients before automatically refilling and shipping a prescription. CMS acknowledged that the requirement can be a burden to plans that use auto-refill programs to increase compliance, but noted that there is concern that the programs can lead to waste and stockpiling.

In an Effort to Increase Vaccination Rates, CMS Urges $0 Co-Pays
Noting that vaccination rates for some vaccines, especially herpes zoster, remain low, CMS reiterates that plans are "encouraged" to cover Part D vaccines at $0 or the lowest co-payment tier for each plan.

CMS Proposes Changes to Measures in Star Ratings
The following measures will be added for the 2019 Star Ratings:

- Statin Use in Persons with Diabetes (SUPD) (Part D): This measure is the percentage of patients between 40 and 75 years old who received at least two diabetes medication fills and also received a statin medication during the measurement period.
- Statin Therapy for Patients with Cardiovascular Disease (Part C): This measure, currently included as a display measure, focuses on the percentage of males ages 21 to 75 and females ages 40 to 75 who were identified as having clinical atherosclerotic cardiovascular disease and were dispensed at least one high or moderate-intensity statin medication during the measurement year.

The following includes changes to existing display measures:

- High Risk Medication (Part D): this measure will remain on the display page for 2019. However, as noted in the 2018 call letter, CMS is proposing to use the updated PQA High Risk Medication (HRM) drug list for that display.
- Drug-Drug Interactions (DDI) (Part D): the PQA updated the drug-drug interactions (DDI) so CMS is proposing to implement the revised list for the 2019 display measure, as discussed in the 2018 call letter.
- Antipsychotic Use in Persons with Dementia (APD) (Part D): CMS is proposing to display the rates for the two population breakouts (community-only residents and long-term nursing home residents) on the 2019 display page and state that they will assess adding this measure to the Star Ratings in the future.
- Use of Opioids at High Dosage and from Multiple Providers in Persons without Cancer (OHDMP) (Part D): this measure will be added to the 2019 Part D display page.

The following measure is being retired:

- Appropriate Monitoring of Patients Taking Long-term Medications and Asthma Medication Ratio (Part C)

CMS Maintains Increased Specialty Cost Threshold, Drops Concerns Over Number of High-Cost Drugs CMS is proposing to maintain the specialty cost threshold at $670 per month for 2018. Noting that ~1% of all prescription drug claims exceed the threshold, the agency stated that it will continue to review data to determine if additional increases are necessary.

2019 Part D Benefit Parameters – Standard Benefit

The majority of the Part D benefit parameters are indexed to an annual percentage increase (API) in average expenditures for Part D drugs. For 2019, this increase will be 1.94 percent. Maximum copayments and out of pocket thresholds are instead based on the consumer price index, and for 2019 will see increases of 1.78 - 1.83 percent.

For 2019, the standard benefit parameters are as follows:

	2018	**2019**
Deductible *Beneficiary responsible for 100% of costs*	$405	$415
Initial Coverage Limit *Beneficiary responsible for 25% of costs; plan responsible for 75%*	$3,750	$3,820
Out-of-Pocket Threshold *Beneficiary liability during deductible, initial coverage limit, and coverage gap* *Manufacturer rebates during coverage gap*	$5,000	$5,100
Estimated Total Drug Spend When Beneficiary Enters Catastrophic Coverage – LIS beneficiaries*	$7,509	$7,654
Estimated Total Drug Spend When Beneficiary Enters Catastrophic Coverage – non-LIS beneficiaries*	$8,418	$8,907
Minimum Cost-Sharing in Catastrophic Coverage Portion of the Benefit – Generic	$3.35	$3.40
Minimum Cost-Sharing in Catastrophic Coverage Portion of the Benefit – Other	$8.35	$8.50

**When a beneficiary's true out-of-pocket (TrOOP) costs reach the Out-of-Pocket Threshold (OOPT), the beneficiary enters catastrophic coverage. The total drug costs at the point when the beneficiary hits the OOPT (and enters catastrophic coverage) will vary for each beneficiary. The numbers presented here represent estimates calculated by CMS of the total drug costs (including OOP costs, manufacturer rebates, and plan-covered costs) the average beneficiary will spend before qualifying for the catastrophic coverage portion of the benefit.*

Part D Benefit Parameters – Non-Standard Benefit
Maximum copayments for both generic drugs and brands stay stable.

	2018	**2019**
Maximum Copayments (3 or more Tiers)		
Preferred Generic	<$20	<$20
Generic Tier	$20	$20
Preferred Brand/Brand Tier	$47	$47
Non-Preferred Drug Tier	$100	$100
Non-Preferred Brand Tier	$100	$100
Injectable Tier	$100	$100
Select Care/Diabetic Tiers	$11	$11
Maximum Co-Insurance (3 or More Tiers)		
Preferred Generic Tier	25%	25%
Generic Tier	25%	25%
Preferred Brand Tier/Brand Tier	25%	25%
Non-Preferred Drug Tier	50%	50%
Non-Preferred Brand Tier	50%	50%
Injectable Tier	33%	33%
Select Care/Diabetes Tier	15%	15%