Important Updates to Medicare Part D in 2016
Frequently Asked Questions

Access, Payment, and Reimbursement Issues

Q: What is CMS doing to monitor for preferred plans that may not meet access standards?
A: In the 2016 Call Letter, CMS finalized a three-pronged approach to ensure convenient access to preferred cost-sharing pharmacies (PCSPs). CMS will publish information in the fall of 2015 on CMS.gov regarding 2016 PCSP access levels for each plan with a preferred pharmacy network. Based on a recommendation from NCPA, the agency also will require plans whose networks are outliers in 2016 to disclose in marketing materials, including websites, that their network offers lower access levels. Further, CMS will work with plans that were extreme outliers in 2014 to address concerns about beneficiary access and marketing representations relating to preferred cost sharing.

Q: What changes can independent pharmacy owners expect to see with regard to Maximum Allowable Cost (MAC) updates?
A: Beginning January 1, 2016, drug pricing based on MAC will be subject to the regulations governing the disclosure and updating of prescription drug pricing standards. Sponsors must establish regular updates (at least every seven days) and indicate the source used by the Part D sponsor for making such updates. When updating prices, Part D sponsors also must disclose the drug prices in advance of their use for reimbursement, and MAC prices must be disclosed to network pharmacies in a manner and format that is useable by the pharmacies, so that pharmacies can validate the prices.

Q: What are DIR fees, and how are they charged?
A: DIR stands for “direct and indirect remuneration” and was initially a term assigned by CMS to address Part D price concessions (e.g. drug manufacturer rebates) that were not captured at the point of sale and would ultimately impact a plan’s gross prescription drug costs. Plan sponsors are required to submit an annual DIR report to CMS, which is used by CMS in tandem with Prescription Drug Event (PDE) data to “true up” what is paid to a Medicare Part D plan by CMS for a given year.

DIR fees can be a broad term designed to encompass a number of different types of fees, including “pay to play” fees for network participation as well as periodic reimbursement reconciliations. Such fees are the terminology that Plan Sponsors are currently using to categorize certain pharmacy network participation fees and the reconciliation of certain contractual terms with actual reimbursement. Sometimes, pharmacies will be assessed a fee to participate in a “preferred” network. These types of fees are typically assessed as a flat per-claim fee or a percentage that is assessed at regular intervals. The fees are essentially price concessions, and Part D plans typically reflect them in their annual DIR report to CMS rather than at the point of sale in PDE records.
Fraud, Waste, and Abuse (FWA)

Q: What is new with FWA training requirements in 2016?

A: CMS is now prohibiting Medicare Advantage (MA) and Prescription Drug Plans (PDPs) from developing and implementing their own compliance training or providing supplemental training materials for their first tier, downstream and related entities (FDRs), including community pharmacies. According to a final rule released in May 2014, MA organizations and PDPs must require pharmacies to utilize CMS's training, which offers them a certificate of completion.

Pharmacies must utilize a training module for fraud, waste, and abuse (FWA) and one for compliance in order to satisfy the training requirement. Pharmacies have a choice of how to fulfill this requirement. They can use the “general compliance” and FWA training modules on CMS's Medicare Learning Network (MLN). Once training is completed, the system will generate a certificate of completion that must be accepted by all MA and PDP sponsors. As an alternative, pharmacies may download and view and/or print the contents of CMS's standardized training modules from the agency's website to incorporate into their own compliance training materials.

Q: What changes are coming related to prescriber information and enrollment?

A: Active and Valid National Provider Identifier (NPI): Effective January 1, 2016, prescriptions will no longer be covered under Medicare Part D if written by a prescriber who does not have a valid Type 1 NPI. When a claim rejects due to an inactive, invalid, or missing NPI and cannot be resolved at the point of sale, the pharmacy must notify the beneficiary the reason the claim could not be covered under Medicare Part D. Part D plans must reject the claim if:

- Non-NPI ID submitted
- Type 1 NPI is inactive
- Invalid NPI is submitted (e.g. Type 2 NPI)

These will be hard edits, and pharmacies can no longer use the submission clarification code (SCC) 49 – “Type 1 NPI available” to communicate with the plan sponsor. However SCC 42 – “Submitted Prescriber ID is Active and Valid with Appropriate Prescriptive Authority” will be permitted.

Medicare Enrollment for Prescribers: Beginning June 1, 2016, physicians and other prescribing professionals who write prescriptions for covered Part D drugs must be enrolled in Medicare or have a valid record of opting out of Medicare for their prescriptions to be covered under Medicare Part D. Pharmacists with prescriptive authority are exempt from this enrollment requirement.

Professional Services and Quality Initiatives

Q: What are the eligibility requirements for MTM in 2016?

A: Sponsors must auto-enroll targeted beneficiaries who meet the eligibility criteria. The beneficiary is considered enrolled unless he/she declines enrollment. Targeted beneficiaries for the MTM program are enrollees who meet all of the following criteria:

1. Have multiple chronic diseases (sponsors cannot require more than 3 as the minimum for eligibility);
2. Are taking multiple Part D drugs (sponsors cannot require more than 8 Part D drugs as the minimum number);
3. Are likely to incur annual Part D drug costs that meet or exceed a certain threshold. The 2016 MTM program annual cost threshold is $3,507.
What should pharmacists be aware of regarding completion of Comprehensive Medication Reviews (CMR)?

CMR completion will become an official measure to Part D Star Ratings in 2016. This measure is based on the PQA-endorsed measure, Completion Rate for CMR, which is used to calculate the percentage of beneficiaries who met eligibility criteria for the MTM program and who received a CMR with a written summary in CMS standardized format. The measure will be assigned a weight of “1” and calculated as a process measure.

2016 Part D Landscape

What does the overall Part D plan landscape look like in 2016?

The following observations can be made about the 2016 Part D plan landscape:

- Overall the number of stand-alone PDPs will decrease from 1,001 to 886—although beneficiaries in most states will have at least 25 plan options available.
- The downward trend is most likely attributable to the reduction in enhanced plan offerings by several parent organizations, including Aetna, Cigna, and Express Scripts.
- Beneficiaries can expect greater cost-sharing, with higher monthly premiums and fewer plans offering $0 deductibles and coverage in the donut hole (gap coverage).

How many national Prescription Drug Plans (PDPs) feature a preferred network in 2016? Which plans allow independent pharmacies into their preferred networks? See table below.

### 2016 Medicare Part D Prescription Drug Plans

<table>
<thead>
<tr>
<th>Plan Name</th>
<th>Parent Company</th>
<th>Preferred Cost-Sharing Network</th>
<th>Preferred Cost-Sharing Network Includes Independents</th>
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<tr>
<td>AARP MedicareRx Preferred</td>
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<tr>
<td>SilverScript Choice</td>
<td>CVS Health</td>
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<tr>
<td>Humana Preferred Rx Plan</td>
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<td>Humana Walmart Rx Plan</td>
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<td>AARP MedicareRx Saver Plus</td>
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<td>Humana Enhanced</td>
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<td>Aetna Medicare Rx Saver</td>
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<td>First Health Part D Value Plus</td>
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* Based on September 2015 enrollment