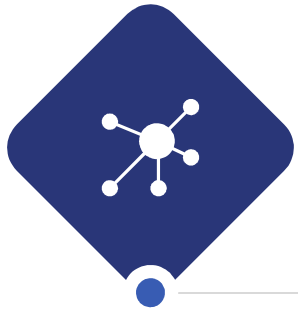
NASP

NATIONAL ASSOCIATION OF SPECIALTY PHARMACY

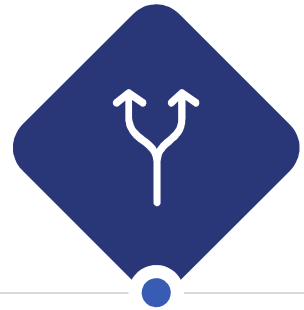
Overview of AWP Provisions for 2017 Contract Year

December 12, 2016

Any Willing Pharmacy (AWP) Background



The Social Security Act *, Medicare Part D regulations ** and the CMS Medicare Prescription Drug Benefit Manual *** all require Medicare Part D Prescription Drug Plans to permit “the participation of any pharmacy that meets the terms and conditions under the plan. Such terms and conditions must be **“reasonable and relevant.”**



CMS guidance to Part D Prescription Drug Plans indicates that baseline conditions of participation established by sponsors must be related to health and safety or financial integrity (e.g. licensure, liability insurance &/or accreditation). Sponsors will negotiate varying payment rates to secure certain pharmacy participation.

CMS has the authority to review all sponsor’s materials to assure AWP compliance and whether standard terms and conditions are reasonable and relevant.

***Section 1860D-4(b)(1)(A); **42 CFR Section 423.120(a)(8)(l); *** Section 50.8.1**

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The Specialty Pharmacy Marketplace

Specialty Pharmacies come in many flavors:

- Independent State, Regional & National Reach
- PBM and/or Plan affiliated or owned
- Integrated delivery networks &/or ACO affiliated or owned
- Disease-specific focus
- Contracted 340(b) provider
- Patient Assistance Dedicated
- Compounding and non-compounded
- Dispensing Oral, Injectable, Implanted and/or Infused Therapies

High-touch SRx patient services vary based on geographic market, disease category, co-morbid conditions, physician medical subspecialty expectations, patient observation and reporting requirements, including REMS programs, patient co-payment requirements, clinical pathways, etc.

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AWP Provisions with Differential Impacts

Some Specialty Pharmacies are adversely impacted by Terms and Conditions that do not apply to their specific service model. This produces differential impact across Specialty Pharmacies from Plan Sponsor terms and conditions. Examples:

- Licensure in all 50 states, Guam and Puerto Rico
  - Not relevant to localized care that SPs provide. Creates unnecessary costs and eliminates patient/provider intimacy key to persistence, compliance and clinical outcomes.
  - Tilts the playing field in favor of larger, national footprint specialty pharmacies affiliated with Plans and PBMs, thereby risking the loss of disease and/or therapy subject matter experts.
- Network Pharmacies required to have access to a broad range of Limited Distribution Drugs or a broad range of drugs across all disease categories.
  - Narrows the number of pharmacies available to patients and referring physician.
- Multiple accreditation requirements (JCAHO, ACHC, URAC, PCAB, etc.) essentially duplicating the same reviews, data reporting and oversights.
- Overly-high minimum threshold of financial assistance for covered beneficiaries.
- Minimum on-site inventories & capacity to ship 1500 scripts a day.
- Capacity and contracted arrangements for home nursing licensure across 50 states, even though the disease or therapies in which the individual SRx specializes do not require home health nursing support to assure patient therapeutic success.

AWP Provisions Create Market Distortions

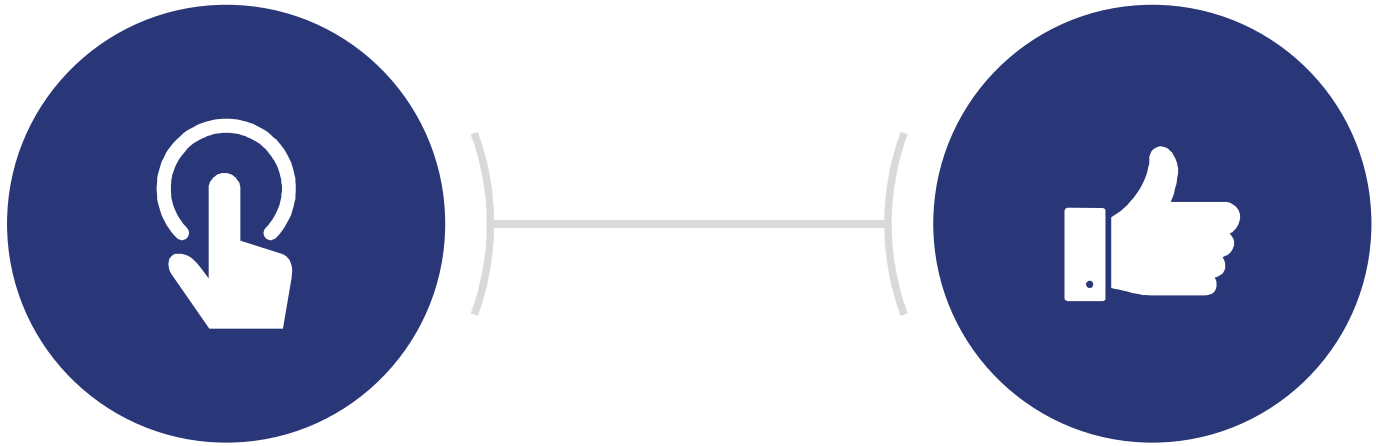
- Terms are not correlated to improving beneficiary car or therapeutic outcomes.
- Plan Sponsors should not set up Benefits Plans in which only one PBM-affiliated SRx satisfies the requirements of network participation. Further PBMs should not be able to subsidize economically affiliated SRx in negative margin.
- Terms result in excluding specialty pharmacies and narrowing pharmacy network access for patients.
- Excluding these pharmacies reduces physician and beneficiary choices by eliminating healthy competition.
- Financial terms are often below margin ***before*** pharmacies begin to provide the patient access, coordination of benefits, patient education, persistency management and/or data reporting requirements.
- Requirements tilt the playing field in favor of size and volume savings as opposed to high-touch, in community provider/patient intimacy.
- Unit cost, reimbursement compression and Plan administrative burdens threaten to eliminate all but high volume, low-touch pharmacy services.

AWP - Next Steps

REQUIRE PLAN SPONSOR TERMS AND CONDITIONS TO:

- Comply with the CMS Manual option for sponsors to “modify some standard terms and conditions to encourage participation by pharmacies.”
- Be demonstrably reasonable and/or relevant to quality of beneficiary care sufficient to justify SRx exclusion and/or narrowing of pharmacy options for beneficiaries.
- Disclose the identities and disease/drug focus of each SRx in the Plan Sponsor’s Network.
- Include in Plan Sponsor SRx Networks all SRx that are contracted with Manufacturers to have access to the Manufacturer’s Limited Distribution Drugs.
- Hold PBM-owned specialty pharmacies to the same standards as all other network pharmacies.
- Transition from a drug-based reimbursement model to a drug plus fee for service model.

Modified Submission Improves Beneficiary Care



CMS can post detailed submissions about SRx Provider Options on the Medicare Plan Finder website.

- Allows beneficiary to choose plan that has an in-network pharmacy for their specialty therapy.
- Expedites access to care because provider can send initial prescription to an in-network pharmacy.

Provide for greater than 30-day notice to beneficiary when current specialty pharmacy is no longer in-network.