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Defining Specialty Pharmacy

The Academy of Managed Care Pharmacy (AMCP) recently published its latest Format for Formulary Submissions, version 3.1. (free download) Starting on page 34, the Format tries to answer two seemingly straightforward questions: What is a specialty drug? What is a specialty pharmacy?

The AMCP's answers, which are intended for manufacturers, certainly won't satisfy every constituent and may be rapidly outdated due to marketplace developments. Nonetheless, I find them useful for clarifying the discussion. Read on and see if you agree.

P.S. Today is the last day for discounted pricing on the *2012–13 Economic Report on Retail, Mail, and Specialty Pharmacies*.

WHAT IS A SPECIALTY DRUG?

Here is the definition of "specialty pharmaceutical" from the AMCP Format:

> *Within the current version of the Format, a product can be classified as a specialty pharmaceutical if:*
>
> - *It requires a difficult or unusual process of delivery to the patient (preparation, handling, storage, inventory, distribution, Risk Evaluation and Mitigation Strategy (REMS) programs, data collection, or administration) or,*
> - *Patient management prior to or following administration (monitoring, disease or therapeutic support systems).*

The AMCP Format is intended as a guide for "…manufacturers of pharmaceuticals, biologics and vaccines who are responding to an unsolicited request from a healthcare system to support reimbursement and/or formulary placement consideration of a new product, new indication, or new formulation of an existing product."

Fair enough. Nonetheless, I note the contrast with health plans, which develop definitions of "specialty" for internal management purposes and to describe benefit coverage to health plan members.

Last year's EMD Serono Specialty Digest found health plans did not always agree on which factors determine if a therapy category should be "specialty." (See chart below.) More than 8 out of ten health plans agreed that "high cost" is a determining factor in identifying a specialty drug. Plans cite average minimum monthly costs of $1,200, although the responses range from $500 to $2,500 per month.

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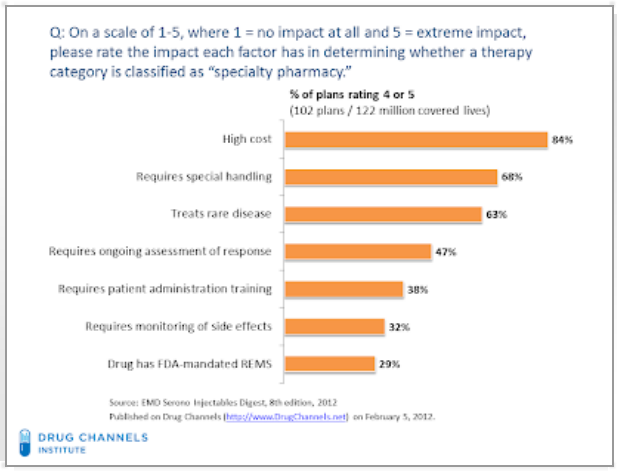

There was less agreement on other factors. Only 68% of health plans consider special handling to be a defining characteristic. Other factors, such as monitoring side effects or patient administration training, received a minority of votes. (For more on the EMD survey, see How Health Plans Manage Specialty Drugs.)

By contrast, AMCP states that "high cost is not enough to define a product as a specialty pharmaceutical, as this definition alone would potentially capture an expensive branded drug with no other special needs for delivery or patient management."

WHAT IS A SPECIALTY PHARMACY?

AMCP defines "specialty pharmacy" with reference to the additional services providing, writing:

> *"Specialty pharmacies are distinct from traditional pharmacies in coordinating many aspects of patient care and disease management. They are designed to efficiently deliver medications with special handling, storage, and distribution requirements with standardized processes that permit economies of scale. Specialty pharmacies are also designed to improve clinical and economic outcomes for patients with complex, often chronic and rare conditions, with close contact and management by clinicians. Health care professionals employed by specialty pharmacies provide patient education, help ensure appropriate medication use, promote adherence, and attempt to avoid unnecessary costs. Other support systems coordinate sharing of information among clinicians treating patients and help patients locate resources to provide financial assistance with out-of-pocket expenditures."*

Here, the AMCP is forced to acknowledge that "specialty pharmacy" reflects a pharmacy's business decision, rather than a regulatory reality. A pharmacy can designate itself a "specialty pharmacy," if its business focus is self-administered specialty pharmaceuticals covered under a patient's pharmacy insurance benefit. In addition to basic product dispensing, patients taking specialty medications often require more complex services than those required for a traditional drug.

Although a majority of the specialty drugs that pharmacies dispense to patients are sold via a specialty pharmacy, any licensed pharmacy can dispense a specialty drug as long as the product can be purchased from a manufacturer or through an authorized wholesale distribution channel. As I discuss in Chapter 8 of *2012–13 Economic Report on Retail, Mail, and Specialty Pharmacies*, many retail pharmacies are dispensing specialty products that can be purchased from the wholesale channel. Unlike specialty products in a limited specialty pharmacy network, these products are in open distribution and can be dispensed by any licensed pharmacy.

The AMCP definition will evolve and reflect the booming specialty marketplace. To compete for the business of dispensing specialty drugs with manufacturer-limited networks, retail pharmacies are pursuing a handful of strategies to build or access the requisite services and technology infrastructure. I'll discuss those strategies, and what they mean for a manufacturer's channel strategy, in a future post.

P.S. Hat tip to Specialty Pharmacy Times.

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Adam, thanks for the post! I've had the "definition" discussion a number of times and hopefully this will bring things into a better focus.

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IRA Rollout, Regulatory Gaps May Drive Major 340B Reforms in 2025, Says Adam Fein of Drug Channels *340B Report*

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Is The Time Right For Congressional Action On 340B? *Forbes*

Lawmakers want FTC to probe big PBMs over private-label biosimilar deals *STAT*

Specialty Pharmacy: The Trends Shaping Best Practices *Pharmaceutical Commerce*

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Federal agency opposes J&J's new 340B discount model, promises to take 'actions as warranted' *Endpoints*

The Next 340B Battle: Discount Duplication With Medicare Negotiated Prices *The Pink Sheet*

The Anti-Competitive Middlemen Harming Pharmacies And Patients *Forbes*

IRA Could 'Crush the 340B Margin,' Force Transparency into Program, Says Adam Fein of Drug Channels *340B Report*

The Opaque Industry Secretly Inflating Prices for Prescription Drugs *The New York Times*

Navigating the Inflation Reduction Act's Impact on Drug Pricing and Health Care *First Report Managed Care*

Biden's War on Medicare *RealClear Policy*

Medicare-Negotiated Drugs May Not Get Favorable Coverage In Part D: Will CMS Intervene? *The Pink Sheet*

Boehringer Ingelheim to cap asthma inhaler out-of-pocket costs at $35 *STAT*

Latest Formulary Exclusions from Top PBMs Demonstrate Issues in the Drug Pricing Landscape *First Report Managed Care*

Drug Channel Entities Are Undergoing Raft of Changes *Spotlight on Market Access*

CVS Removes Humira From Formulary — But the Fine Print Is Key *Radar on Drug Benefits*

CVS Plans to Overhaul How Much Drugs Cost *The Wall Street Journal*

Cigna-Humana Merger Is Likely to Face Antitrust Challenge *The Wall Street Journal*

Amazon Once Inspired Fear in the Health-Care Industry. No Longer *Bloomberg*

Why Your Neighborhood Pharmacy Isn't So Friendly Anymore *The Wall Street Journal*

Rite Aid Bankruptcy Follows Years of PBM Misadventure *Radar on Drug Benefits*

What CVS Stands to Gain by Setting Up Biosimilar Subsidiary Cordavis *MedCity News*

Ohio senator says Medicare drug cost negotiations will save money. Others aren't so sure *WSYX*

Drug Benefit Firms Devise New Fees That Go to Them, Not Clients *Bloomberg*

CVS Health Dives As Blue Shield Of California Taps Mark Cuban, Amazon In Challenge To PBM Model *Investor's Business Daily*

A Big Health Insurer Is Ripping Up the Playbook on Drug Pricing *The Wall Street Journal*

Patients already paying price for PBMs diverting copay cash meant for needy *ABC6*

PBMs Keep New Biosimilars on Equal Footing With Best-Selling Humira, *Radar on Drug Benefits*

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Average salaries for retail pharmacists grows for first time in three years *MM+M*

Coherus works with Mark Cuban to sell biosimilar Humira at steep discounts *STAT*

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Drug Middlemen Accused of Price Fixing by Ohio Attorney General *The Wall Street*

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Drugmakers push back on a clever tactic employers use to avoid paying for specialty medicines *STAT*

A Softbank-backed pharmacy startup is working to tackle a $300-billion-a-year prescription drug crisis *Fortune*

Tackling cancer while battling the insurance system *The Washington Post*

'It is legal extortion': Diabetics pay steep price for insulin as rebates drive up costs *USA Today*

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Kroger Health expands Prescription Drug Safety Education program to more than 470 schools

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STAT+: Medicare director, at JPM conference, gives tips on how to lead the nation's largest payer

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