Legal Issues Affecting Physician Dispensing and Pharmacies
Staying Ahead of Payor & Regulatory Trends
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Glossary

• “Dispensing Physician Practices” refers to practices that dispense medication pursuant their plenary medical license, where permitted by law. They do not hold a pharmacy license.

• “Physician-Owned Pharmacies” refers to practices the dispense medication through a licensed retail pharmacy. The licensed retail pharmacy may be the same entity as the medical practice.

• “Community Oncology Practices” refers broadly to both Dispensing Physician Practices and Physician-Owned Pharmacies.
NETWORK ACCESS
**CVS Caremark “Slow Rolling” Dispensing Physicians**

<table>
<thead>
<tr>
<th>Issue:</th>
<th>While Caremark had originally allowed dispensing physician to apply and participate in its networks, Caremark has started to “slow-roll&quot; or deny a number of credentialing applications submitted by non-grandfathered dispensing practices. The denials are often vague and list many “potential” reasons. Caremark will also sit on documents for extended periods of time, only to ask for documents that were either provided and have since lapsed due to Caremark’s delay (i.e., insurance policies, licenses, etc.), or additional documents that could have been provided at the initial submission. The clear pattern by Caremark shows intention to prevent or limit further dispensing physician practices participation.</th>
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<tbody>
<tr>
<td>Who Is Being Impacted (and Extent):</td>
<td>Dispensing physicians. After a poll of membership, at least 10 practices have been impacted, and it is primarily dispensing physician practices that have submitted applications in September 2017 or after are experiencing this issue.</td>
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| What Can Be Done | • Demand Letters  
• Complaints to CMS  
• Litigation Against Caremark |
# Prime Therapeutics Attack on Dispensing Physicians

| Issue: | Prime Therapeutics has stated that as of January 29, 2018, Prime “will no longer be accepting PSAO additions with a pharmacy type of Dispensing Physician. Prime is no longer seeking new pharmacies with this dispensing classification.”

As of January 15, 2019, Prime issued its first “with or without cause” termination notice to a practice on the basis that Prime no longer accepts dispensing physicians in its pharmacy networks. |
|---|---|
| Who Is Being Impacted (and Extent): | Initially set to affect all new dispensing physician practices that were seeking admission into Prime’s pharmacy networks on or after January 29, 2018.

Now appears to impact any dispensing physician practice in Prime’s networks, including grandfathered dispensing physician practices. |
| What Can Be Done: | • Complaints to CMS  
• Complaints to State DOBs  
• Litigation Against Prime Therapeutics |
Potpourri of Payor Problems

Network Access

- MedImpact Denials of Dispensing Physicians
- OptumRx M&R Extra Ordinary Drugs Network
- Anthem of California No Longer Allowing Physicians to Dispense Orals
- BSBC of Minnesota and Michigan Exclusivity with AllianceRx Walgreens
- EmblemHealth Medicaid Managed Care Creating Exclusive Network
- Aetna Requiring Use of CVS Specialty by Pennsylvania State Employees for IV Medications
Any Willing Provider

• Federal Any Willing Provider Law - 50 States & Washington D.C. (Medicare Part D)
• Federal Freedom of Patient Choice Law - 50 States & Washington D.C. (Medicare Part D)
• State Any Willing Provider Laws
• State Anti-Mandatory Mail Order Laws

33 States have some form of Any Willing Provider Law
Type of Plan Impacts What Law Applies

United States Healthcare System types of coverage as of Summer 2017
Total Pop.: ~323.5M

- Category total higher due to some people having more than 1 type of coverage

Charles Gaba/ACASignups.net

MEDICAID/CHIP: ~74.4M
(~9M dual eligibles)

MEDICARE: ~57M
(~9M dual eligibles)
The Employee Retirement Security Act ("ERISA"), 29 U.S.C. §§ 1001 - 1461, is a federal law passed in 1974 setting forth the standards for administering employee health benefits, including the processing of health claims under the Plan.

ERISA requires that every Plan include a Summary Plan Description ("SPD") unless an exemption applies.

ERISA is a federal statute that preempts state laws.

However, states still have right to regulate "the business of insurance".

This ERISA "preemption" might apply to other State laws aimed at protecting pharmacies.
COVERAGE & REIMBURSEMENT
Prescription Trolling

The first fill is the pharmacy’s most expensive claim

- Coordination with Prescriber
- Prior Authorization Assistance
- Patient Assistance Programs
- Patient Training/Skilled Nursing Administration
Preventing Patient Steering

Practices Must Demand PBM Adherence to the Law

Practices May Inform Patients of Their Rights

Complaints to State Regulatory Agencies May Also Be Effective
Generic Effective Rate (GER) & Brand Effective Rate (BER)

- Technically a form of DIR
- Sets an average, aggregate network discount on generics and/or brand drugs
- Measured on a network level
- Very opaque in implementation and execution
PBM establishes a MAC price of $19
Generic Effective Rate (GER) & Brand Effective Rate (BER)

If GER is AWP-87%

And pharmacy filled too many of these products, it could owe money back

Generic Effective Rate & Brand Effective Rate

Acquisition Cost AWP

Drug 1 Drug 2 Drug 3 Drug 4 Drug 5

AWP-88% AWP-86% AWP-84% AWP-80% AWP-78%
Part D plans and PBMs have expanded percentage-based DIR fees

CMS issues Proposed Rule to move all pharmacy price concessions to point of sale

Existential crisis for many specialty pharmacies

Multiple providers have commenced actions against PBMs and plan sponsors

Industry organizations release multiple white papers
Unreasonable Medicaid Pricing: What Can Be Done?

Litigation

Government Affairs

Appeal to Myers & Stauffer
Forecasting Changes in Drug Pricing Policies

- Rebate Safe Harbor NPRM
- Senate Finance Committee Hearing
- American Patients First Blueprint
REGULATORY THREATS
USP 797 Enforcement and Compliance

• The United States Pharmacopeia (USP) is releasing a set of standards relating to sterile compounding, applicable dispensing oncology practices

• USP Chapter <797> describes a number of requirements applicable to sterile compounding, including responsibilities of compounding personnel, training, facilities, environmental monitoring, and storage and testing of finished preparations

• While the standards themselves do not have the force of law, some government legislatures and authorities have adopted the standards, in whole or in part, into their laws, in addition to the FDA adopting USP standards into FDA rules and guidances
USP 797 Enforcement and Compliance

• Implementation timeline:
  • June 1, 2019 - Intended Publication Date of the revised USP Chapter <797> in USP 42-NF 37
  • December 1, 2019 - Anticipated Official Date for USP Chapter <797>
  • Will require substantial preparation to assure compliance and stakeholders should implement tailored compliance plan
USP 800 Enforcement and Compliance

• USP is releasing a set of standards (USP General Chapter <800>) applicable to any stakeholders involved in the handling of hazardous drugs in healthcare settings, and includes requirements pertaining to activities from receipt to disposal, engineering controls and personal protective equipment, medical surveillance, personnel training, and hazard communication

• December 1, 2019 is expected official date

• Substantial questions on potential reach of standards (as OSHA may enforce regardless of state adoption)

• Would require significant investment in infrastructure, in addition to P&Ps on Hazardous Drug Handling and Hazardous Drug Compounding
Board of Pharmacy and Jurisdictional Reach

• In many states, a physician can delegate generally to an individual they deem qualified (i.e., nurse or medical technician) in order to assist in accomplishing the physician’s professional responsibilities
  • This could include delegating certain pharmacy and dispensing functions
• Boards of Medicine and Medical Practice Acts generally govern actions of physicians
  • Boards of Pharmacy and Pharmacy Practice Acts, however, sometimes will govern all dispensing of prescription drugs, in addition to all individuals licensed by the Board of Pharmacy (i.e., pharmacists and pharmacy technicians)
• Recently, certain state Boards of Pharmacy have begun inspecting dispensing physician clinics
  • While they lack jurisdiction to take action against the physicians themselves, they have been focusing on the Board of Pharmacy licensees working under the supervision of a physician and “practicing pharmacy” outside a licensed pharmacy
Legal Strategies for Practices

Patient Angle
- Many plans afford different rights/remedies for impacted patients
- Practices can engage impacted patients directly or practice to obtain Assignments of Benefits to pursue claims (including grievances, claims, appeals, or fair hearings) on behalf of the patients upon execution of Appointment of Representative
- May open up class action possibilities

Complaints to Agencies
- Providers can submit detailed complaints to relevant regulatory agencies, including state Medicaid agencies, CMS, Boards of Pharmacy and Departments of Insurance
- Can achieve greater success through a “sea” of complaints

Out-of-Network Claims
- For providers facing network exclusion, may be able to submit out-of-network claims using paper claim submission forms
- Many plans cover out-of-network pharmacy services and require PBM to process cumbersome paper claims
- Has caused PBMs to admit providers rather than deal with administrative burden of paper claim processing

Litigation/Arbitration
- Begins with the filing of a “Dispute Notice” or “Grievance” per the terms of the contract
- Actions would be in arbitration or litigation, depending on the particular PBM
- Causes of action would include breach of contract, breach of implied covenant of good faith, tortious interference, breach of any willing provider laws, and violations of unfair trade practice laws
Legal Strategies for Practices

• 50+ state surveys on 6 topics (AWPL, DIR, Audit Laws, PBM Licensure, MAC and Prompt Pay)
• Pointers on gaps and areas for improvement
• Propose additional surveys on USP <797> and <800> implementation and compliance

• These are available for download and use by practices on their own
• Includes complaints to agencies
• Not much feedback on use or effectiveness

• PBM Network Exclusion Letter and First Fill Only Letter
• Only 4-5 have utilized service
• Often issues with gathering necessary data to prosecute claim

$500 Flat Fee

Maps

Letters

PBM Trolling
Letters and Templates

Star Rating
Patient Letter and Templates

• These are available for download and use by practices on their own
• PBM take Star Ratings seriously
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Copay Accumulators

• **Definition and Application:**
  • Copay Accumulators are policies that some PBMs have enacted to stop manufacturer-sponsored copayment cards or other manufacturer-assistance programs from counting towards a patient’s deductible or annual out-of-pocket maximum. AKA accumulator adjustment programs; coupon adjustment programs; out-of-pocket protection programs.
  • Apply only to commercial plans

• **Some of the Negative Effects:**
  • Lower Medication Adherence
  • Decreased Use of Specialty Drugs

• **Some States Have Taken Action:**
  • **Virginia and West Virginia:** Enacted Bills that require a PBM to include any amounts paid by an enrollee or on behalf of an enrollee towards out-of-pocket maximum or cost sharing requirement.
  • **Maryland** has recently proposed a similar bill but it has not yet been enacted.
How to Challenge Copay Accumulators

- Review Summary Plan and Plan documents
- Under most plans, patients can either make a grievance or a coverage determination:
  - A coverage determination is the decision the insurer will make as relates to payments for the patients’ benefits, prescriptions costs, and other coverage issues
  - A grievance is a general statement of dissatisfaction about the plan (i.e. copay accumulator)
- Providers can pursue action against an insurer on behalf of a patient if the patient does either of the following:
  - Assigns his/her benefits to the provider
  - Appoints the provider as the patient’s Power of Attorney
Questions?

Thank You!

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