PATIENT CARE IN PERIL?
THE FUTURE OF PHYSICIAN DISPENSING

Webinar
Monday, October 17, 2017

Speakers

Moderator:
Jan E. Berger, MD, MJ
Editor in Chief
American Journal of Pharmacy Benefits

Ricky Newton, CPA
Director of Financial Services and Operations
Community Oncology Alliance

Joshua Cox, Pharm.D., BCPS
Pharmacy Director
Dayton Physicians Network

Jonathan E. Levitt, Esq.
Founding Partner
Frier & Levitt

Ray Bailey, RPh
Director of Pharmacy
Florida Cancer Specialists

Jesse C. Dresser, Esq.
Partner
Frier & Levitt

David J. Coury
Chief Executive Officer
UroGPO
Our Agenda Today

1. Welcome & Introductions
   • Jan Berger, MD, MJ, Editor in Chief, American Journal of Pharmacy Benefits

2. Overview of the issue & why it matters
   • Ricky Newton, CPA, Director of Financial Services and Operations, Community Oncology Alliance

3. PBM White Paper overview & legal perspective
   • Jonathan E. Levitt, Esq., Founding Partner, Frier & Levitt
   • Jesse C. Dresser, Esq., Partner, Frier & Levitt

4. Patient Impact & Practice Implication
   • Joshua Cox, Pharm.D., BCPS, Pharmacy Director, Dayton Physicians Network
   • Ray Bailey, RPh, Director of Pharmacy, Florida Cancer Specialists
   • David J. Coury, Chief Executive Officer, UroGPO

5. Q&A Session
About the Community Oncology Pharmacy Association (COPA)

ACHC Accreditation

Learn more & join us at: www.coapharmacy.com

Innovating and Advocating for Community Cancer Care

FDA Approved Drugs for Oncology (Chemotherapy and Supportive Care)

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<td>Totals 2011 to 2015</td>
<td>34</td>
<td>37</td>
<td>71</td>
<td>48%</td>
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Announcements about CVS/Caremark

February 19, 2016

VIA UPS

Congressman Ed Whitfield (KY-01)
2184 Rayburn House Office Building
Washington, DC 20515

Re: Inquiry on Oncology Association of West Kentucky

Insert from this Letter

Dear Congressman Whitfield:

Outside of not meeting our “general” requirements for being a community pharmacy with a broad assortment of drug therapies, our ongoing regulatory review also made clear that CMS considers such physician dispensing facilities as out-of-network providers. CMS Medicare Part D rules define “sponsor networks” as pharmacy only networks, and “retail pharmacy” is defined as a licensed pharmacy from which enrollees can purchase a drug without being required to receive medical services. CMS has also explicitly stated that “covered Part D drugs that are appropriately dispensed and administered in a physician’s office will be subject to the same treatment under our out-of-network access rules.” Based on a recent inquiry to CMS, we understand that CMS has not changed its policy towards non-pharmacy dispensers.
Announcements about CVS/Caremark

Important Update Regarding Caremark’s In-Office Dispensing Services

As a valued member of our In-Office Dispensing program, we wanted to share with you an important update regarding Caremark’s In-Office Dispensing services. Beginning in January 1, 2017, pharmacy dispensing class of trade will no longer be included in Caremark’s Medicare Part D network.

Caremark made this decision in accordance to the CMS Medicare Part D rules that define a “system” network as a pharmacy-only network. CVS considers provider dispensing declines to be out-of-network, and has stated that drugs dispensed and administered by a physician’s office "will be subject to the same treatment under out-of-network rules.”

This decision will impact any new or existing physician dispensing and is not specific to any particular pharmacy service administration organization (PSAO) or partner medication. It will not impact physician-owned pharmacies.

McKesson Specialty Health and AmnSourceHealth are working through the full implications of this “system” at this time. As it relates to in-office dispensing services, The McKesson In-Office Dispensing team will support any process that wishes to connect to a pharmacy model (in states where allowed), and will work with the practice to ensure all state specific rules and regulations are met. We are also actively exploring strategies for purchase or operating pharmacy dispersions in states that do not allow a physician-owned pharmacy class of trade.

We understand the importance of this move to our members and will keep you updated as this process moves forward.

Sincerely,
The McKesson Specialty Health In-Office Dispensing Team

Why this Issue is so important

- If CVS/Caremark is successful in defining what a retail pharmacy is and who should be allowed to be in network then…
  - Our patients suffer from lack of care at the point of service, uncoordinated and delayed start of treatment.
  - Costs in the health system increase due to lower adherence, persistence, and waste when patients receive their medications outside of the physicians office.
  - Others PBM’s will follow without regard to how this impacts patient care
  - It will get worse: CVS will continue to narrow their definition of what a retail pharmacy is - as might others - and further disallow retail pharmacies to dispense in physician clinics.
  - CVS is redefining state pharmacy laws that have already defined what and who can operate pharmacies within physician clinics and whether retail or physician dispensing is allowed.
Impact Nationally

- We know of 872 practices with in-house physician dispensing or retail pharmacies that could be impacted:
  - 521 in house physician dispensing oncology practices nationally representing 2,226 oncologists that will not be able to dispense as of January 1, 2017 for CVS/Caremark Part D plans.
  - 351 oncology practices nationally representing 1,492 oncologists with retail pharmacies within their clinics (These practices are not directly affected as of the first of the year but could be in the future).

What COA is Doing

- Hired law firm Frier Levitt, specializing in pharmacy issues, to fight for community oncology:
  - Letter to CVS - August 3rd
  - Call with CVS - August 24th
  - White paper on PBMs - August 30th

- Coordinating practices
  - State and Federal legislator outreach - Ongoing
  - Patient outreach - Ongoing
  - More…
### National Stats on Available Part D Plans for Patients

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<th>Processors</th>
<th>Prescription Drug Plans</th>
<th>Insurance Company Name</th>
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<td>Argus</td>
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<td>7.04%</td>
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<tr>
<td>CVS/Caremark</td>
<td>19</td>
<td>26.76%</td>
</tr>
<tr>
<td>Catamaran</td>
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<td>11</td>
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<td>Magellan</td>
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<tr>
<td>Rx Options/Envision</td>
<td>1</td>
<td>11.27%</td>
</tr>
<tr>
<td>Overall Totals with CVS</td>
<td>71</td>
<td>50 *</td>
</tr>
<tr>
<td>Overall Totals without CVS</td>
<td>54</td>
<td>32</td>
</tr>
</tbody>
</table>

*These 50 Insurance Companies make up 1,120 total plans available nationally.*

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### Stats on Available Part D Plans for Patients **

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<td>13.51%</td>
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<tr>
<td>Catamaran</td>
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<td>2.70%</td>
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<td>10.81%</td>
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</tr>
<tr>
<td>Overall Totals without CVS</td>
<td>26</td>
<td>13</td>
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</tbody>
</table>

** States that we know are not allowed to have retail pharmacies and sometimes no pharmacies at all (PA, NY, CA, CT, ME, CO, NV, NH, MA, MD, IA)
OVERVIEW OF WHITE PAPER ON RECENT CVS/CAREMARK ACTIONS

Jonathan E. Levitt, Esq. and Jesse C. Dresser, Esq.
WHAT IS CVS/CAREMARK DOING?

After notification, Oncology Association of West Kentucky submitted an application to be placed back into its retail pharmacy network. As such, they do not carry a full array of medications for patients as would a community pharmacy. Also, they are also a “cloud door” facility, only treating the patients under their care. Our pharmacy network is comprised of community pharmacies that provide a wide array of drug therapies to our members.

Outside of not meeting our “general” requirements for being a community pharmacy with a broad assortment of drug therapies and operating pharmacy service, we also made clear that CMS considers such pharmacy dispensing facilities as network pharmacy sites. CMS Medicare Part D rules define “network pharmacy” as a pharmacy not under the control of our pharmacy network members, and a “retail pharmacy” is defined as a licensed pharmacy from which individuals purchase a drug without being required to receive medical services. CMS has also explicitly stated that “several Part D drugs that are appropriately dispensed and administered in a physician’s office will be subject to the same treatment under our out-of-network access rules.” Based on a recent inquiry to CMS, we understand that CMS has not changed its policy towards non-pharmacy dispensers.

1) You do not meet CVS/Caremark’s definition of a “retail pharmacy”

2) Dispensing Physicians are out-of-network providers under Medicare Part D

WHO WILL BE AffECTED?

- Some industry stakeholders (including CVS/Caremark) have “said” that beginning January 1, 2017, physician dispensing class of trade will no longer be included in Caremark’s Medicare Part D network and this action “will not impact physician-owned pharmacies”...
WHO MAY BE AFFECTED?

However, CVS/Caremark may seek to exclude others if “retail” terms and conditions are not met:

- Carry a full array of medications for patients
- Must not be a “closed door” facility, only treating patients under their care
- Provide a wide array of drug therapies

FINANCIAL MOTIVES OF CVS/CAREMARK

BEFORE

Physician in-office administration of IV chemotherapy

NOW

Oral oncolytics dispensed by physicians or retail pharmacies

CVS/Caremark uses PBM to shift business to wholly-owned pharmacies
WHERE IS THIS COMING FROM?

- CVS/Caremark points to CMS Medicare Part D Rules relating to “pharmacy only” “sponsor networks,” and physician dispensing facilities as “out-of-network” providers under 42 C.F.R. 423.124(a)(2)
- September 2016: CVS/Caremark responds publicly to White Paper, stating that they received guidance from CMS and that CMS agreed with their position

ENTER FRIER LEVITT’S WHITE PAPER
Medicare Modernization Act of 2003

- Amended Title XVIII of the Social Security Act – “Health Insurance for the Aged and Disabled” (Title 42, Chap. 7, Subchapter XVIII / 42 U.S.C. §§ 1395, et seq.)

Prohibition Against Federal Interference (42 U.S.C. 1395)

- Any Willing Provider Law (42 U.S.C. 1395w-104)
- Patient Freedom of Choice (42 U.S.C. 1395a)

These sections have the weight of law

Enabling statute (42 U.S.C. 1395a-100, et seq.)

- Nothing in this subchapter shall be construed to authorize any Federal officer or employee to exercise any supervision or control over the practice of medicine or the manner in which medical services are provided, or over the selection, tenure, or compensation of any officer or employee of any institution, agency, or person providing health services; or to exercise any supervision or control over the administration or operation of any such institution, agency, or person.
Medicare Modernization Act of 2003

- **Any Willing Provider Law** (42 U.S.C. 1395w-104)
- **Patient Freedom of Choice** (42 U.S.C. 1395a)
- **Prohibition Against Federal Interference** (42 U.S.C. 1395)
- **Absolutely nothing in the statute about physician dispensing**
- **Enabling statute** (42 U.S.C. 1395hh-100, et seq.)

...but as limited by the Administrative Procedure Act (5 U.S.C. 551, et seq.)

Authorizes HHS (through CMS) to promulgate regulations...

Absolutely nothing in the statute about physician dispensing

Enabling statute (42 U.S.C. 1395hh-100, et seq.)

Authorizes HHS (through CMS) to promulgate regulations...
These are regulations and are less controlling than specific laws to the contrary

Medicare Part D Regulations
(Title 42, Part 423 of the Code of Federal Regulations)

(a) Out-of-network access to covered Part D prescription drugs. A Part D plan sponsor must have adequate access to covered Part D prescription drugs when the enrollee obtains such drugs at an out-of-network pharmacy or at a pharmacy located in another state. A Part D plan sponsor must ensure that enrollees have adequate access to covered Part D prescription drugs from pharmacies within the Part D plan's network, which includes retail, mail-order, and institutional pharmacies under contract with the Part D plan sponsor to provide covered Part D prescription drugs at negotiated prices to enrollees.

Pharmacy network contracting requirements. In establishing a contracted pharmacy network, a Part D plan sponsor offering qualified prescription drug coverage—(i) Must contract with any pharmacy that meets the Part D plan sponsor’s standard terms and conditions; and (ii) May not require a pharmacy to accept insurance risk as a condition of participation in the Part D plan sponsor’s contracted pharmacy network.

Contract provisions (AWP Regs).
(42 C.F.R. 423.505)

Special rules for out-of-network access
(42 C.F.R. 423.124)

Definition of “pharmacy”
(42 C.F.R. 423.12)

Access to covered Part D drugs
(42 C.F.R. 423.320)
The explicit statutes contained in the Social Security Act (i.e., AWPL, Freedom of Choice) control... …over any regulation adopted by CMS to the contrary (i.e., physician dispensers as out-of-network).

Moreover, the regulations also contain specific sections relating to AWPL, definition of a "pharmacy," etc., which support physician dispensers' position.

CLINICAL AND ECONOMIC BENEFITS OF PHYSICIAN DISPENSING

- Outcomes Based Reimbursement and the Medicare-sponsored Oncology Care Model
- Patient Adherence and Monitoring
PATIENT IMPACT & PRACTICE IMPLICATION

Ray Bailey, RPh
Florida Cancer Specialists

Joshua Cox, Pharm.D., BCPS
Dayton Physicians Network
Patient Impact

- Disruptions in Service
- Potential loss of Financial Assistance
- Lost of Practice Integrated EMR Empowered Pharmacy Services
- Long delays in access as oral chemotherapy scripts must be referred to outside specialty pharmacy
- Patient losses practice based oral adherence programs
- Lost of direct physician oversight of oral chemotherapy dispensing
- Potential for more waste when scripts dispensed outside practice

Business Implications for Practice

- Massive loss of Revenues from high volume of oral regimens
- Financial stresses that will impact entire practice
- Loss of control of oral chemotherapy in alternative payment models (OCM)
- Diminished control of regimens that include oral and IV products. Often causing delays
- Decreased purchasing volumes could affect GPO contracts
- Loss of Revenues will inevitably decrease the value added services practices can provide patients on oral chemotherapy
- Will negatively impact patient outcomes and quality standards
PATIENT IMPACT & PRACTICE IMPLICATION: UROLOGY PERSPECTIVE

David J. Coury
Chief Executive Officer
UroGPO
UroGPO In Office Dispensing Initiative
“A Patient’s Right to Choose”

- 199 Community Based Practices
- 2,932 Healthcare Providers
- 76 Dispensing Practices

Community Urologists are facing exact same battle as Community Oncologists to keep control over patient care

David Coury
http://www.urogpo.us.com/
Questions?

- Type your question into the WebEx Q&A box:
  1. Look for the green control box at the top of your screen.
  2. Move your mouse over to expand the full box.
  3. Select the ▼ “Options” on the right.
  4. Select Q&A and a new box will pop up.
  5. Type your question in the box – be sure to send to “All panelists”

Thank you for attending!

- Full PBM and physician dispensing White Paper is available for download:

- Slides will be distributed to those that RSVPd later this week.

- Stay up to date & subscribe to newsletters:
  - COA updates & activities [www.CommunityOncology.org](http://www.CommunityOncology.org)
  - AJPB news & perspective at [www.AJPB.com](http://www.AJPB.com)