Legislative and Regulatory Update: Implications for Pharmacists

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CPE Information

• Target Audience: Pharmacists and Pharmacy Technicians
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• Activity Type: Knowledge-based
Disclosures

Michael Baxter, Jenna Ventresca and Alicia Kerry Mica: “...declare no conflicts of interest, real or apparent, and no financial interests in any company, product, or service mentioned in this program, including grants, employment, gifts, stock holdings, and honoraria.”

The American Pharmacists Association is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.
Learning Objectives:

At the completion of this knowledge-based activity, participants will be able to:

1. List examples of recent federal legislative activity that impact the practice of pharmacy.
2. Describe new federal regulations and activities related to the practice of pharmacy.
3. State the current efforts at the federal level to reimburse pharmacists for their services.
1. Which one of the following pieces of legislation was signed into law in 2018?
   a. Drug Quality and Security Act (DQSA)
   b. Ensuring Seniors Access to Pharmacy Act
   c. Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT for Patients and Communities Act)
   d. Comprehensive Addiction and Recovery Act
2. Which beneficiaries would be eligible to receive services (and pharmacists eligible to receive reimbursement for these services) if the Pharmacy and Medically Underserved Areas Enhancement Act had passed and was signed into law?

a. All Medicare and Medicaid beneficiaries
b. Medicare beneficiaries who live in medically underserved communities

c. Only patients at federally qualified health centers
d. All Medicare patients
3. What did Congress accomplish regarding drug pricing?

a. Passed legislation to directly negotiate national prescription drug prices for Medicare (the same as the Veterans Affairs (VA) and Department of Defense (DOD))

b. Passed legislation allowing the federal government to import prescription drugs in shortage from other countries

c. Passed legislation prohibiting pharmaceutical benefit manager (PBM) “gag clauses”

d. Passed legislation removing the safe harbor for drug rebates across the federal government paid to insurance plans and PBMs
Assessment Question #4

4. As of August 2019, which of the following will be true regarding hazardous waste pharmaceuticals?

a. In all states, healthcare facilities may not sewer hazardous waste pharmaceuticals

b. All states must adopt 40 CFR part 266 subpart P – Standards for the Management of Specific Hazardous Wastes and Specific Types of Hazardous Waste Management Facilities

c. All states must stop recognizing nicotine as an acute hazardous waste

d. Authorized states must adopt 40 CFR part 266 subpart P – Standards for the Management of Specific Hazardous Wastes and Specific Types of Hazardous Waste Management Facilities
Regulatory Update
Advocating for the Profession - Pharmacists at the Table

In November and December, APhA met with Health and Human Services (HHS) Secretary Alex Azar where we covered Provider Status and opioid related services, Direct and Indirect Remuneration (DIR) fees and rebates, and a broad ranging discussion on drug pricing and the impact on patient care.

https://twitter.com/SecAzar?lang=en
Pharmacists Get a Well-Deserved Vote of Confidence in New Federal Report

- Calls for states to expand their scope of practice statutes to allow pharmacists and other health care providers to practice to the top of their license, utilizing their full skill set and training
- Recommends the federal government and states should consider legislative and administrative proposals to allow nonphysician providers to be paid directly for their services
- However, it’s not all champagne and roses - A few additional provisions in the report recommend scrutinizing existing “any willing provider” laws and increasing the use of selective contracting, despite the negative impact this would have on patient choice, access to care, and competition

Drug Pricing

• What’s the “Good News” –
  • “The prices for prescription drugs fell 0.6% during the 12 months 2018. This is the largest decline in prescription drug prices in almost half a century (46 years).” –Council of Economic Advisors, November 11
  • “Adjusted for general inflation, the prices of prescription drugs fell almost 3% (about 2.8%) during the 12 months 2018.” –Council of Economic Advisors, November 11

• What’s the “Bad News” –
  “But many problems remain. This January, drug companies once again announced large price increases — by one analysis averaging around 6 percent per drug. This annual practice of large price hikes must stop, and prices must come down.” –HHS Secretary Azar, January 29
Drug Pricing – Administration Actions

• POTUS signs law prohibiting “Gag Clauses” for Part D, MA, Fully Insured (Exchange/Obamacare and small group) plans and employer (large group) plans (October)
  • CMS PBM “Gag Clause” prohibition letter to Part D plans (May)

• CMS Proposed International Pricing Index Model (IPI) (December)

• Part D Rule Request for Information (RFI) (November 2017) / Trump Drug Pricing “Blueprint” RFI (May)/ Part D Drug Pricing Proposed Rule (December) – Including rebates / pharmacy price concessions (including DIR fees) at the Point-of-Sale (POS) / permit additional formulary exemptions for “protected drug classes”
Drug Pricing – Administration Actions

• HHS Office of Inspector General (OIG) Proposed Rule to remove safe harbor protection for drug rebates paid to insurance plans and PBMs (January/February 2019)

• Food and Drug Administration (FDA) Importation Working Group established to make recommendations for drugs that are off-patent or off-exclusivity and produced by one manufacturer (single-source) (July 2018) (no recommendations-met in August)
Drug Pricing – Administration Actions on Rebates

- OIG Proposed Rule to remove safe harbor protection for drug rebates paid to insurance plans and PBMs (1/31)
  - Would expressly exclude from safe harbor protection under the Anti-Kickback Statute rebates on prescription drugs paid by manufacturers to pharmacy benefit managers (PBMs), Part D plans and Medicaid managed care organizations, unless they are shared with patients at the pharmacy counter
Drug Pricing – Administration Actions on Rebates

- OIG Proposed Rule to remove safe harbor protection for drug rebates paid to insurance plans and PBMs (continued)
  - Creates a new safe harbor for “fixed fee” service arrangements between drug manufacturers and PBMs to still provide “pharmacy benefit management services”

- While seniors' Medicare premiums are likely to go up, anywhere from eight to 22 percent (but more likely around 5), HHS says those hikes will be offset by lower out-of-pocket spending on high-cost drugs
Drug Pricing – APhA HOD

- APhA House of Delegates (HOD) Policy
  - APhA strongly supports patient access to affordable and cost effective medications
  - APhA supports a “transparent pricing” framework which would eliminate hidden discounts, free goods and other subtle economic devices throughout the supply chain
Drug Pricing – APhA HOD

• APhA has been linking drug pricing to provider status/ pharmacists’ service
  • Broader than just the price of medication
  • Medication management and patient education is an important part of controlling costs, especially as medications become more expensive and complex
  • The most costly drugs are those not taken or not taken correctly
CMS: Annual Activity Relevant to Pharmacists

**Part D Rule:**
November-January – Draft; March/April – Final version

**Mechanism for announcing significant policy changes to the Part D and Medicare Advantage (MA) prescription drug plans (MA-PDs)**

**This year:** Part D – Drug Pricing Rule – Draft; December – Final version (TBD)

**Call Letter:**
February – Draft; April – Final version

**Sets forth changes in Medicare payment methodology for Part D/MA plans as well as benefit parameters for the defined standard benefit received by Part D plan beneficiaries—information used for plan sponsors to submit bids

**Physician Fee Schedule (PFS) Rule:**
September – Draft; November – Final version

**Outlines payment requirements for physicians and other providers**
APhA continues to urge the CMS to better utilize pharmacists in its current and new programs and initiatives which aligns with its move toward value-based delivery and payment. Examples include:

- 2015 Medicare Access and Children's Health Insurance Program (CHIP)Reauthorization Act (MACRA) law (Measuring 4 categories: Quality, Interoperability, Improvement Activities, Cost) - including the Merit-Based Incentive Payment System (MIPS) and Advanced Alternative Payment Model (APMs);
- Accountable Care Organizations (ACOs);
- Enhanced Medication Therapy Management (MTM) Model, etc.

**CMS: APhA Advocacy Opportunities**

<table>
<thead>
<tr>
<th>Opportunities</th>
<th>Barriers</th>
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<tbody>
<tr>
<td>APhA estimates pharmacists can also contribute to over 25% of the more than 270 current quality measures, as well as many of the improvement activities and promoting interoperability measures under MIPS</td>
<td>CMS does not recognize pharmacists as “Eligible Clinicians” – “Thus, nurses and pharmacists would not be able to participate in MIPS,” which also prevents delivering electronic/telehealth services</td>
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- NOTE: 2018 MACRA and Physician Fee Schedule Updates have been combined
- Accountable Care Organizations (ACOs);
CMS: APhA Advocacy Opportunities

• **Reimbursement:** Examples include: MACRA, “Incident-to” services; Evaluation and Management (E&M) services; Chronic Care Management (CCM), Transitional Care Management (TCM), preventive care, immunization(s), ‘Any Willing’ Pharmacy requirements

• **Recognition - Impact on Value and Quality:** CMS and private payor reimbursement continues to move toward quality - APhA continues to identify ways specific services and mechanisms pharmacists can improve quality.
  • Examples include ACO, Part D regulations and Physician Fee Schedule
CMS: Recent Activity Increasing Pharmacist Recognition

- Final ACO Rule/ Coordination of Pharmacy Care for ACO Beneficiaries with Part D Plans

“One commenter expressed concern regarding the differences between Part D Medication Management Therapy (MTM) and medication management services provided through coordinated care models, and specifically noted variation in beneficiary eligibility for MTM services, depending on their Part D plan. The commenter asked that CMS address current barriers to beneficiary eligibility for MTM before making any additional changes to policies under the Shared Savings Program to improve care coordination with pharmacies.”

CMS Response: “We thank the commenters for their input on the coordination of pharmacy care for ACO assigned beneficiaries. As we plan for any future updates and changes to the Shared Savings Program, we will consider this feedback from commenters before making any proposals related to the coordination of pharmacy care.”
FDA: DQSA Compounding

Drug Quality and Security Act (DQSA)
Signed into law on November 27, 2013

Compounding Quality Act (CQA)
Establishes Outsourcing Facilities

Drug Supply Chain Security Act (DSCSA)
Also known as "Track and Trace"
FDA: Recent DQSA Compounding Activity

- 2018 Compounding Policy Priorities Plan (Compounded drugs pursuant to valid patient-specific prescriptions)
  - New Draft MOU (If # of Compounded Rx is < 50% in any Month) (9/7)
    - National Association of Boards of Pharmacy (NABP) Consultation Required – “distribution” is not “dispensing”, potential new definition of “intrastate” distribution
- Revised Draft 503B Guidance - “503B Light”- a new risk-based approach where FDA will consider how current good manufacturing practice (CGMP) requirements should be applied to compounders in light of the size and scope of an outsourcing facility's operations (12/10)
- Insanitary Conditions at Compounding Facilities (Revised Draft Guidance) (9/25)
FDA: Recent DQSA Compounding Activity

• FDA intends to announce a plan soon to improve the information available about compounded topical pain creams, with the intention to “...help inform reimbursors' and the medical community's decisions about these products” (TBD)

• Pharmacy Compounding Advisory Committee (PCAC) meetings on bulk substances list—Bulk Substances guidances (503A-Final rule) (2/15), (503B- Final Guidance) (3/1)
Health and Human Services (HHS) & CMS: Recent DQSA Compounding Activity

- OIG: August 10 report identifies 547 pharmacies and 124 prescribers with questionable billing patterns (one California pharmacy billed $7.2 million for compounded drugs in 2016, compared to $60,000 the prior year)

CMS: “It is important to note that pharmacies that specialize in compounded drugs may have billing patterns that differ from traditional pharmacies and may not be indicative of fraud”

MEMORANDUM
From: CMS
Date: August 10, 2018

Part D plans to:
- Incorporate training on fraud schemes into ongoing training programs
- Continue efforts to ensure medical necessity of Part D compounds through the use of utilization management tools and when considering exception requests
### USP: Recent Compounding Activity

<table>
<thead>
<tr>
<th>Chapter</th>
<th>Comments Submitted</th>
<th>Official Implementation Deadline</th>
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<tr>
<td>Revisions to USP General Chapter &lt;795&gt; Pharmaceutical Compounding – Nonsterile Preparations</td>
<td>July 31, 2018</td>
<td>December 1, 2019</td>
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<tr>
<td>Revisions to USP General Chapter &lt;797&gt; Pharmaceutical Compounding – Sterile Preparations</td>
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<td>December 1, 2019</td>
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<td>New USP General Chapter &lt;825&gt; Radiopharmaceuticals – Preparation, Compounding, Dispensing, and Repackaging</td>
<td>November 30, 2018</td>
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<td>USP General Chapter &lt;800&gt; Hazardous Drugs—Handling in Healthcare Settings</td>
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<td>December 1, 2019</td>
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FDA: Drug Supply Chain Security Act (DSCSA) (1 of 2)

**Phase 1: Lot Level Traceability**
- Authorized trading partner verification (1/2015)
- Suspect/illegitimate product identification and notification (3/2016)
- Transaction data (1/2015 & 3/2016)

**Phase 2: Product Identifier (PI)**
- Manufacturers add PI to unit/case, and build a database (11/18 & 11/17)
- Re-packagers add PI to unit/case (11/18)
- Wholesaler: PI transactions only (11/19)
- Dispenser: PI transactions only (11/20)

**Phase 3: Unit Level Traceability**
- Unit-level traceability for all supply chain stakeholders (11/2023)
- Track and exchange unit-level serialized data (11/2023)
FDA: DSCSA (2 of 2)

- Additional Provisions for FDA:
  - Small pharmacy (25 or fewer employees) technology and software assessment on package-level tracing
  - Establish and evaluate pilot projects on enhancing supply chain safety/security
  - Regulations establishing enhanced drug distribution security system for interoperable electronic tracing of product at the package level
  - Final guidance on interoperable data exchange standards for secure package level product tracing
FDA: DSCSA - What is a product (Section 581(13))?

- Products covered by DSCSA
  - Prescription drug in finished dosage form for administration to a patient without further manufacturing (such as capsules, tablets, lyophilized products before reconstitution)
- Products not covered by DSCSA
  - Blood or blood components intended for transfusion
  - Radioactive drugs or biologics
  - Imaging drugs
  - Certain IV products
  - Medical gas
  - Homeopathic drugs
  - Lawfully compounded drugs
**FDA: DSCSA - What is a transaction (Section 581(24))?**

- Transfer of product where a change of ownership occurs

<table>
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<th>Exemptions/ Exclusions from “transaction”</th>
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<td>Medical gas distribution</td>
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<td>Document</td>
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<td>Definitions of Suspect Product and Illegitimate Product or Verification Obligations</td>
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<td>Standardization of Data and Documentation Practices for Product Tracing</td>
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<td>Waivers, Exceptions and Exemptions from the Requirements of Section 582 of the Federal Food, Drug and Cosmetic Act</td>
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<td>Grandfathering Policy for Packages and Homogenous Cases of Product without a Product Identifier</td>
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<tr>
<td>The Product Identifier for Human, Finished, Prescription Drugs: Question and Answer</td>
</tr>
<tr>
<td>Verification Systems Under the Drug Supply Chain Security Act for Certain Prescription Drugs</td>
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</table>
FDA: DSCSA - Product Identification (Serialization)

- Draft guidance indicated the National Drug Code (NDC) must be in human readable format on product identifiers
- Linear bar codes should not be replaced by 2D data matrix bar code
FDA: DSCSA - Identifying Grandfathered Products

Tip: If the transaction history or transaction information shows a sale before 11/27/2018, the dispenser may consider the product grandfathered.

FDA: DSCSA - Notify FDA of Illegitimate Products

- FDA 3911
- Dispensers and other trading partners must notify FDA of illegitimate products within 24 hours of determination (Note: must also notify other trading partners)
- If product is determined to be legitimate, then traders must notify FDA

Source: Food and Drug Administration, Form FDA 3911, available at: https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM513940.pdf
FDA: DSCSA Enforcement

• February 2019: FDA submits warning letter to a wholesale distributor for significant violation of the verification requirements of DSCSA

• This was the first time FDA issued a warning letter under DSCSA

• Three specific violations referenced:
  • Failure to respond to illegitimate product notifications as required, which includes identifying all illegitimate product subject to such notifications in your possession or control and quarantining such product (section 582(c)(4)(B)(iii)).
  • Failure to quarantine and investigate suspect product (section 582(c)(4)(A)(i)).
  • Failure to keep, for not less than 6 years, records of the investigation of suspect product and the disposition of illegitimate product (sections 582(c)(4)(A)(iii) and 582(c)(4)(B)(v)).

Source: Food and Drug Administration, Inspections, Compliance, Enforcement, and Criminal Investigations, enforcement letter available at: https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm631088.htm
FDA: DSCSA Enforcement - What happened?

• Pharmacy customer provided the wholesale distributor with notice that multiple pharmacy locations received bottles that were supposed to contain potent opioid pills

• The pharmacy opened the bottles to discovery the contents were not the correct medications; the opioids were replaced with other non-opioid medications

• Wholesale distributor performed internal investigation
  • Key finding: opioid medication was replaced while in their possession or control

• FDA concluded the wholesale distributor did not sufficiently respond to the notification that they may have distributed illegitimate products

• Distributor did not notify other pharmacy customers who may have received products with the same lot number or National Drug Code
FDA: DSCSA Pilot Projects

- Background: FDA must establish 1+ pilot projects in coordination with trading partners
- FDA accepted requests to participate until March 11, 2019
- Goal: To assist drug supply chain stakeholders in developing the electronic, interoperable system that will identify and trace certain prescription drug products as they are distributed within the United States, for example:
  - System attributes needed to implement the requirement to utilize a product identifier for product tracing and verification
  - Assessing the ability of supply chain members to:
    - (1) Identify, manage, and prevent the distribution of suspect and illegitimate products
    - (2) Exchange product tracing information across the pharmaceutical distribution supply chain in an electronic and interoperable manner
- Final reports to be provided to FDA 30-45 days after completing a pilot project; FDA intends to post the final program report online

FDA: Anticipated DSCSA Guidances and 2019 Activity

- Proposed Licensing Program Under the Drug Supply Chain Security Act (included on 2018 agenda)
- Proposed Accreditation Program Under the Drug Supply Chain Security Act (included on 2018 agenda)
- Pilot Projects
- Key deadline: Wholesale distributors must engage in transactions only with product identifiers (November 2019)
FDA’s Website: Pharmacists: Utilize DSCSA Requirements to Protect Your Patients

- Free DSCSA continuing education
- General information
- Pharmacist poster on DSCSA responsibilities

Environmental Protection Agency (EPA) : Hazardous Waste (HW) Pharmaceuticals & Amendment to the Nicotine Listing (P075) Final Rule (“HW Final Rule”) 

- Establishes 40 CFR part 266 subpart P
- Effective August 2019 with variable implementation deadlines; state dependent
- New standards for the management and disposal of pharmaceutical hazardous waste generated by healthcare facilities and reverse distributors
- Bans sewering
- Removes over-the-counter nicotine replacement therapy from acute hazardous waste listing
Healthcare facilities **will:**
- Be able to accumulate hazardous waste pharmaceuticals on site without a Resource Conservation and Recovery Act (RCRA) permit for 365 days (an increase of 275 days over current regulations)
- Have basic training requirements
- Need to comply with new regulations
- Be able to dispose of over-the-counter nicotine replacement therapy as non-hazardous waste
Healthcare facilities **will not**:

- Become a large quantity generator when it generates more than 1kg of acute hazardous waste pharmaceuticals in one month (Part 266 Subpart P has no generator categories)
- Have to comply with satellite accumulation area regulations
- Need to specify hazardous waste codes on manifests
- Need to keep track of how much hazardous waste pharmaceuticals generated per month
- Need to segregate acute and non-acute hazardous waste pharmaceuticals
- Be allowed to intentionally sewer (effective in all states August 2019)
EPA: HW Final Rule - New Terms Under Part 266 Subpart P

- Pharmaceutical
- Hazardous waste pharmaceutical
  - Non-creditable hazardous waste pharmaceutical
  - Potentially creditable hazardous waste pharmaceutical
  - Evaluated hazardous waste pharmaceutical
- Healthcare facility
- Reverse distributor
EPA: HW Final Rule - Flow of Prescription and Non-Prescription HW Products

Rx Hazardous Waste Pharmaceutical

1st Reverse Distributor

2. Potentially Creditable

Healthcare Facility

3. Evaluated

No further evaluation or verification of manufacturer credit is necessary

2nd Reverse Distributor

1. Non-Creditable

HW TSDF

Non-Rx Hazardous Waste Pharmaceuticals (e.g., OTCs)

1st Reverse Logistics Center

Not Solid Waste

IF there is a reasonable expectation of use/reuse or reclamation (status quo)

2nd Reverse Logistics Center

Part 262 (status quo)

Non-creditable Part 266 Subpart P (new)

EPA: HW Final Rule - What is meant by “pharmaceutical”? 

- Pharmaceutical means any drug or dietary supplement for use by humans or other animals
  - Any electronic nicotine delivery system (ENDS)
    - E.g., e-cigarette or vaping pen
    - Any liquid nicotine/e-liquid packaged for retail sale for use in ENDS
      - E.g., prefilled cartridges or vials
  - Includes but is not limited to over-the-counter drugs, homeopathic drugs, compounded drugs, pharmaceuticals remaining in non-empty containers, clean-up material from spills of pharmaceuticals
  - Does not include: sharps or medical waste
Hazardous waste pharmaceutical means

• A pharmaceutical that **is a solid waste** as defined in § 261.2, and
  • Exhibits one or more characteristics identified in part 261 subpart C; or
  • Is listed in part 261 subpart D.

• A pharmaceutical is **not a solid waste**, as defined in § 261.2, and therefore not a hazardous waste pharmaceutical, if it is legitimately used/reused (e.g., lawfully donated for its intended purpose) or reclaimed.

• An over-the-counter pharmaceutical, dietary supplement, or homeopathic drug is **not a solid waste**, as defined in § 261.2, and therefore not a hazardous waste pharmaceutical, if it has a reasonable expectation of being legitimately used/reused (e.g., lawfully redistributed for its intended purpose) or reclaimed.
EPA: HW Final Rule - What is meant by “non-creditable hazardous waste pharmaceutical”?

Non-creditable hazardous waste pharmaceutical means a prescription hazardous waste pharmaceutical that does not have a reasonable expectation to be eligible for manufacturer credit or a nonprescription hazardous waste pharmaceutical that does not have a reasonable expectation to be legitimately used/reused or reclaimed. This includes but is not limited to:

- investigational drugs;
- free samples of pharmaceuticals received by healthcare facilities;
- residues of pharmaceuticals remaining in empty containers;
- contaminated personal protective equipment;
- floor sweepings; and
- clean-up material from the spills of pharmaceuticals.
EPA: HW Final Rule - What is meant by “potentially creditable hazardous waste pharmaceutical”?  

• Potentially creditable hazardous waste pharmaceutical means a prescription hazardous waste pharmaceutical that has a reasonable expectation to receive manufacturer credit and is
  • (1) in original manufacturer packaging (except pharmaceuticals that were subject to a recall);
  • (2) undispensed; and
  • (3) unexpired or less than one year past expiration date. The term does not include evaluated hazardous waste pharmaceuticals or nonprescription pharmaceuticals including, but not limited to, over-the-counter drugs, homeopathic drugs, and dietary supplements.
EPA: HW Final Rule - What is meant by “evaluated hazardous waste pharmaceutical”?

- Evaluated hazardous waste pharmaceutical means a prescription hazardous waste pharmaceutical that has been evaluated by a reverse distributor in accordance with § 266.510(a)(3) and will not be sent to another reverse distributor for further evaluation or verification of manufacturer credit.
EPA: HW Final Rule - What is a “healthcare facility”?

- **Healthcare facility** means any person that is lawfully authorized to
  - (1) Provide preventative, diagnostic, therapeutic, rehabilitative, maintenance or palliative care, and counseling service, assessment or procedure with respect to the physical or mental condition, or functional status, of a human or animal or that affects the structure or function of the human or animal body; or
  - (2) Distribute, sell, or dispense pharmaceuticals, including over-the-counter pharmaceuticals, dietary supplements, homeopathic drugs, or prescription pharmaceuticals

- Note: “Healthcare facility,” includes long-term care facilities, pharmacies, hospitals, mail-order pharmacies and compounding pharmacies, among others
EPA: HW Final Rule - Options for Very Small Quantity Generators (VSQG)

• Opt into Part 266 Subpart P and comply with all its provisions OR
• Use the optional provisions of Part 266 Subpart P:
  • (1) A VSQG healthcare facility can continue to send potentially creditable hazardous waste pharmaceuticals to a reverse distributor
  • (2) A VSQG healthcare facility can send its hazardous waste pharmaceuticals off-site to another healthcare facility, provided the receiving healthcare facility is
    • Operating under Part 266 Subpart P and meets certain conditions, or
    • A Large Quantity Generator operating under Part 262 and meets the conditions for off-site consolidation
• **Reminder:** A VSQG generates 100 kilograms or less per month of hazardous waste or one kilogram or less per month of acutely hazardous waste
• Check state law/regulatory activity to determine Subpart P compliance deadlines
• Submit one-time notification indicating operating under Subpart P (Site ID Form: 8700-12)
• Train all personnel managing non-creditable hazardous waste pharmaceuticals
• Make hazardous waste and creditable/non-creditable waste determinations (unless all waste is managed as hazardous waste)
  • Health care facilities may accumulate both their hazardous and non-hazardous waste pharmaceuticals in the same container; the containers should then be distinguished as “potentially creditable” or “non-creditable” and then as “prescription” or “non-prescription”

• Adhere to:
  • Labeling requirements
  • Container standards
  • Accumulation times
  • Shipping standards, including those related to manifests and rejected shipments

• Be aware of controlled substance exemptions and changes to nicotine P075 listing
### Standards

<table>
<thead>
<tr>
<th>Standards</th>
<th>Non-creditable HW Rx</th>
<th>Potentially creditable HW Rx</th>
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<tbody>
<tr>
<td><strong>Labeling</strong></td>
<td>- Accumulation container have labeling stating “Hazardous Waste Pharmaceuticals”</td>
<td>No labeling</td>
</tr>
<tr>
<td></td>
<td>- No HW codes or other labeling requirements</td>
<td></td>
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<tr>
<td><strong>Container Standards</strong></td>
<td>- Structurally sound, will not react with contents</td>
<td>No container standards</td>
</tr>
<tr>
<td></td>
<td>- Remain closed and secured; prevent unauthorized access to its contents</td>
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<tr>
<td><strong>Accumulation Time</strong></td>
<td>- 1 year maximum</td>
<td>- No time limit</td>
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<tr>
<td></td>
<td>- Universal waste-like standards</td>
<td>- No standards</td>
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## Standards

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<tbody>
<tr>
<td>Shipping standards</td>
<td>- Manifest required</td>
<td>- Common carrier (e.g., UPS, U.S. Postal Service, FedEx) acceptable; no HW transporter requirements</td>
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<tr>
<td></td>
<td>- Shipping healthcare facility to use “PHARMS” on manifest instead of HW codes</td>
<td>- Shipper must receive delivery confirmation</td>
</tr>
<tr>
<td></td>
<td>- HW transporter required</td>
<td>- No manifest required</td>
</tr>
</tbody>
</table>

### Destination

- HW treatment, storage and disposal facility

Typically, a reverse distributor (Rx pharmaceuticals) or reverse logistic center (retail items and non-Rx pharmaceuticals)
EPA: HW Final Rule - New Empty Container Standards

• Residues remaining in “RCRA empty” containers are not regulated as HW
• Four different standards for following types of containers found in a healthcare setting:
  • Stock/dispensing bottles (1 liter or 10,000 pills) and unit-dose containers → remove contents
  • Syringes → fully depress plunger
  • IV Bags → fully administer contents (additional options for non-acute HW pharmaceuticals)
  • Other containers → Acute HW pharmaceuticals cannot be RCRA empty; non-acute HW pharmaceuticals have additional options
• Triple rinsing of containers with acute hazardous waste pharmaceuticals is not required/allowed anymore
Controlled substances that are also HW pharmaceuticals are exempt from RCRA, so long as the following conditions are met:

- Option 1: Not sewer, managed in compliance with DEA regulations and destroyed by a method DEA indicated meets their non-retrievable standard
- Option 2: Combusted at one of the following types of permitted facilities
  - Large or small municipal waste combustor
  - Hospital, medical and infectious waste incinerator
  - Commercial and industrial waste incinerator
  - Hazardous waste combustor

Household waste pharmaceuticals collected in DEA authorized collection receptacles (kiosks) are also exempt
EPA: HW Final Rule - Sewer Prohibition

• HW pharmaceuticals may not be sewered (e.g., no disposal down the drain and no flushing)
• Sewer prohibition applies to:
  • All healthcare facilities, including healthcare facilities that are VSQGs
  • All reverse distributors
• DEA controlled substances that are also HW
• EPA strongly discourages sewering of any pharmaceuticals by any entity
• **Effective in ALL states August 2019**
Currently, acute hazardous waste includes all P-listed wastes

The Final Rule amends the P075 list for HW to remove FDA-approved over-the-counter nicotine replacement therapies (e.g., patches, gums, lozenges)
  • Can be discarded as nonhazardous waste

Other unused formulation of nicotine ARE still considered acute hazardous waste when discarded (e.g., e-liquids/e-juices in e-cigarettes, cartridges, vials; nicotine used in research and manufacturing)

States MAY choose to adopt EPA’s amendment
EPA: HW Final Rule - Effective Dates and State Adoption Timeline

February 22, 2019

- Rule officially published

August 21, 2019

- Sewer ban effective in ALL states
- Nicotine amendment effective in non-authorized states
- Subpart P effective in non-authorized states

July 1, 2021

- Authorized states (no statutory amendment needed) must adopt Subpart P

July 1, 2022

- Authorized states that require a statutory amendment must adopt Subpart P

EPA: HW Final Rule - Looking for more information:

- EPA Webinar: https://clu-in.org/conf/tio/HazWastePharmaceuticals/

Final Rule: Management Standards for Hazardous Waste Pharmaceuticals and Amendment to the P075 Listing for Nicotine

Rule Summary

The EPA Acting Administrator signed the final rule, titled, “Management Standards for Hazardous Waste Pharmaceuticals and Amendment to the P075 Listing for Nicotine” on December 11, 2018.

- View a pre-publication version of the final rule

This final rule establishes cost-saving, streamlined standards for handling hazardous waste pharmaceuticals to better fit the operations of the healthcare sector while maintaining protection of human health and the environment.
Pain Management and Opioid Use Disorder: Key Activities in 2018 and early 2019

• Advisory on Naloxone and Opioid Overdose (April 2018)
• Part D – Overutilization Monitoring System
• SUPPORT for Patients and Communities Act signed into law (Oct 2019)
• Start of consensus study and report related to indication-specific prescribing guidelines (August 2018)
• FDA expands and updates Risk Evaluation and Mitigation Strategy (REMS) program
• HHS Pain Management Best Practices Inter-Agency Task Force
# Pain Management and Opioid Use Disorder: Congress - SUPPORT for Patients and Communities Act (1 of 2)

<table>
<thead>
<tr>
<th>Topic</th>
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<tbody>
<tr>
<td>Mandatory e-prescribing (Medicare)</td>
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<tr>
<td>Mandatory e-prior authorization functionality (Medicare)</td>
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<tr>
<td>Medicare drug management program (“lock-in”)</td>
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<tr>
<td>Medicaid drug management program (“lock-in”)</td>
<td>❌</td>
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<tr>
<td>Medicaid drug utilization review</td>
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<td>Telehealth / Telemedicine (e.g., DEA regulations for special registration)</td>
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<td>Medicare (Welcome to Medicare package, initial physical exam, and annual wellness visit)</td>
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<td>FDA Prescribing Guidelines</td>
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<td>FDA Packaging and Disposal (REMS)</td>
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<tr>
<td>Mental health records/ history of SUD (Jessie’s Law)</td>
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## Pain Management and Opioid Use Disorder: Congress - SUPPORT for Patients and Communities Act (2 of 2)

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<td>Pharmacists’ corresponding responsibility resources and materials</td>
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<td>Drug Disposal Grants (DEA)</td>
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<td>Prescription Drug Monitoring Program enhancements</td>
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<td>• Medicaid providers required to note experiences in record systems</td>
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<td>• “Qualified prescription drug monitoring program”</td>
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<td>Suspicious orders</td>
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<td>Pharmacy controlled substance delivery of MAT injection/implantation medications</td>
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<td>Align 42 CFR Part 2 with HIPAA</td>
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<tr>
<td>Expand MTM Part D eligibility</td>
<td>✗</td>
</tr>
<tr>
<td>Expand DATA waiver eligibility to pharmacists</td>
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</tbody>
</table>
Pain Management and Opioid Use Disorder: CMS - Medicare Opioid Related Activity

• Drug management programs (pharmacy lock-ins)

• Opioid Safety Alerts
  • NEW (as of Jan. 1 2019): Opioid care coordination edit (at 90 MME)
  • Optional high MME hard edit (200 MME or more and may include prescriber/pharmacy counts)
  • Duplicate long-acting opioid therapy soft edit
  • Concurrent opioid-benzodiazepine soft edit
  • 7-day supply hard edit on initial opioid prescription fills (acute pain)

Pain Management and Opioid Use Disorder: CMS 2020 Medicare Advantage and Part D Advance Notice and Draft Call Letter

- CMS evaluating opioid safety alerts and drug management programs
- Pain management and complementary and integrative treatments in Medicare Advantage
- Encouraging Part D sponsors to provide lower cost-sharing for opioid-reversal agents, such as naloxone
- Star ratings: Updating methodology for measures currently on or under consideration for display page

Pain Management and Opioid Use Disorder: Enforcement Activity

• Temporary restraining order was issued, for the first time, to stop two pharmacies, their owner and three pharmacists from dispensing controlled substances

• Action supported by the Drug Enforcement Agency (DEA)

HHS: Pain Management Best Practices Inter-Agency Task Force

- Authorized by the Comprehensive Addiction and Recovery Act of 2014
- Membership include government and non-governmental representatives, including two pharmacists
- Draft report currently available for public comment until April 2019
- Addresses clinical best practices, cross-cutting clinical and policy best practices and reviews the Centers for Disease Control (CDC) guideline

Pain Management and Opioid Use Disorder
Upcoming Activity: Additional APhA Resources

- Pain, Palliative Care and Addiction Special Interest Group
- Ongoing continuing education
- Institute on Substance Use Disorders (May 29 - June 2, 2019)
- Issue briefs
- Practice tools

FDA: Innovative Approaches for Nonprescription Drug Products

• Draft guidance released in July 2018
• Use of innovative tools to support self-selection
• Examples:
  • Mobile apps with questions to help someone determine whether the use of a nonprescription drug product is appropriate
  • New types of drug labeling, in addition to the current labeling
• More indications available for use without a prescription
• Future proposed rulemaking: “Nonprescription Drug Product with an Additional Condition for Nonprescription Use” (anticipated release in 2019)

Communications: FDA developing a new rapid-response tool
Flexible framework that adequately evaluates product safety and promotes innovation
Botanical Safety Consortium: a public-private partnership to promote scientific advances in evaluating the safety of botanical ingredients and mixtures in dietary supplements

APhA Advocacy Issues

APhA Statements (2018-2019)

Centers for Medicare & Medicaid Services

- Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2020 (February 2019)
- Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses (January 2019)
- Medicare Programs: International Pricing Index (January 2018)
- Medicare Program; Medicare Shared Savings Program (October 2018)
- Medicare Program: Revisions to Payment Policies

Food and Drug Administration

- Identifying the Root Causes of Drug Shortages and Finding Enduring Solutions; Public Meeting; Request for Comments (January 2019)
- Verification Systems Under the Drug Supply Chain Security Act for Certain Prescription Drugs (December 2018)
- Memorandum of Understanding Addressing Certain Distributions of Compounded Human Drug Products Between the States and the Food and Drug Administration; Revised Draft; Availability (December 2018)
- Insanitary Conditions at Compounding Facilities, Guidance for Industry (November 2018)
- Product Identifiers Under the Drug Supply Chain Security Act Questions and Answers (November 2018)
- Innovative Approaches for Nonprescription Drug Products; Draft Guidance for Industry (September 2018)
- Indications and Usage Section of Labeling for Human Prescription Drug and Biological Products – Content and

**Additional Issue Areas APhA Follows**

- Quality measures
- Billing
- Health IT
- Radiopharmaceuticals
- Biologics
- Drug Shortages
- Online pharmacy and supply chain safety
- Medication disposal
- REMS
- Labeling
- Rx to Over-the-Counter (OTC) switches
- Tests, devices, pharmacogenomics
- Adverse Drug Events
- Partial fills
Congressional and Legislative Update
## Major Congressional Actions in 2018 on Health Care

### SUPPORT for Patients and Communities Act

**Background**
- Includes reforms to Medicare and Medicaid to combat the opioid crisis
- Advances mental health treatment and addiction recovery initiatives
- Increases efforts and resources to combat illicit synthetic drugs from crossing the boarder
- Encourages the development of other non-opioid drugs

**Status:** Signed into law on 10/24/2018

### Delayed ACA Cadillac and Medical Device taxes

**Background**
- Placed a two-year delay on the Affordable Care Act’s 40% excise tax on high-value health care plans, until 2022
- Delayed an ACA excise tax on medical devices from going into effect until 2020, and retroactively removed the tax for the 2017 tax year

**Status:** Signed into law on 1/22/2018

### Individual mandate repeal

**Background**
- Congress reduced the individual mandate penalty to $0 to begin in 2019
- The penalty changed as part of tax reform legislation passed in December of 2017

**Status:** Signed into law on 12/20/2017

---

Overview: SUPPORT for Patients and Communities Act

Bill overview
• Includes Medicare, Medicaid and public health reforms to combat the opioid crisis
• Advances treatment and recovery initiatives
• Increases efforts and resources to combat illicit synthetic drugs from crossing the border
• Encourages the development of nonopioid drugs

Points of controversy
• Critics say the legislation makes legal and regulatory adjustments to combat the opioid crisis but does not adequately fund a wide expansion of addiction treatment

Sources: www.congress.gov; National Journal
Major congressional actions in 2018 on drug pricing

- Closed the Medicare Part D donut hole early
  - Added into the February omnibus bill
  - Requires pharmaceutical manufacturers to pay 70% of the brand-name drug costs for beneficiaries in the coverage gap

- Repealed pharmacist “gag orders”
  - Bans contracts between pharmacy benefit managers and insurance companies that don’t allow pharmacists to tell beneficiaries how they could pay less for medicine

- Investigated opioid manufacturers/marketers
  - The Energy and Commerce Subcommittee on Oversight held multiple hearings investigating major pharma companies, distributors and makers of overdose reversal drugs

- Passed an opioid-related group of bills
  - Gives Medicare/Medicaid recipients access to more addiction and mental health services
  - Requires Medicaid use opioid monitoring programs
  - Allows NPs and PAs to prescribe buprenorphine

Composition of the 116th Congress: House

Partisan makeup of the House compared to the previous Congress

- Seats flipped R to D (Total: 43)
- Seats flipped D to R (Total: 3)
- Not yet called (Total: 1)  Vacant (2)

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<td>199</td>
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<tr>
<td>Democrat</td>
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<td>235</td>
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<tr>
<td>Not yet called or vacant</td>
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Source: National Journal; As of February 25, 2019
House Democratic Leadership

- Speaker: Nancy Pelosi (CA)
- Majority Leader: Steny Hoyer (MD)
- Majority Whip: Jim Clyburn (SC)
- Assistant House Speaker: Ben Ray Lujan (NM)
- Caucus Chair: Hakeem Jeffries (NY)
- Democratic Congressional Campaign Committee Chair: Cheri Bustos (IL)
House Republican Leadership

- Minority Leader: Kevin McCarthy (CA)
- Minority Whip: Steve Scalise (LA)
- Republican Conference Chair: Liz Cheney (WY)
- National Republican Congressional Committee Chair: Tom Emmer (MN)
- Republican Conference Vice Chair: Mark Walker (NC)
- Republican Conference Secretary: Jason Smith (MO)
- Republican Policy Committee Chair: Gary Palmer (AL)
Composition of the 116th Congress: Senate

Partisan makeup of the Senate compared to the previous Congress

- Seats flipped R to D (Total: 2)
- Seats flipped D to R (Total: 4)

*Independents Sanders and King, who caucus with the Democrats, have been included in the Democratic tally

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<tr>
<td>Not yet called</td>
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Source: National Journal As of February 11, 2019
New U.S. Senators

- Mike Braun (R-IN)
- Josh Hawley (R-MO)
- Jacky Rosen (D-NV)
- Kevin Cramer (R-ND)
- Marsha Blackburn (R-TN)
- Mitt Romney (R-UT)
- Rick Scott (R-FL)
Senate Republican Leadership

- Senate Republican Leader: Mitch McConnell (KY)
- Assistant Leader: John Thune (SD)
- Chair of Republican Conference: John Barrasso (WY)
- Policy Committee Chair: Roy Blunt (MO)
- Vice Chair Republican Conference: Joni Ernst (IA)
- Chair of the National Republican Senatorial Committee: Todd Young (IN)
Senate Democratic Leadership

- Senate Democratic Leader and Chair of the Conference: Charles E. Schumer (NY)
- Democratic Whip: Richard J. Durbin (IL)
- Assistant Democratic Leader: Patty Murray (WA)
- Chair, Democratic Policy and Communications Committee: Debbie Stabenow (MI)
- Vice Chair, Democratic Conference: Elizabeth Warren (MA)
- Vice Chair, Democratic Conference: Mark Warner (VA)
- Chair, Steering Committee: Amy Klobuchar (MN)
- Chair, Outreach: Bernie Sanders (VT)
- Vice Chair, Democratic Policy and Communications Committee: Joe Manchin (WV)
- Senate Democratic Conference Secretary: Tammy Baldwin (WI)
- Chair, Democratic Senatorial Campaign Committee: Catherine Cortez Masto (NV)
• Pharmacist Provider Status
  • 115th Congress (2017 – 2018)
    • 297 Co-sponsors of H.R. 592
    • 56 Co-sponsors of S. 109
    • Over 60 co-sponsors of these bills did not return for the 116th Congress

• Prescription Drug Pricing

• DIR fees at POS Proposed Rule
Health Issues before 116th Congress

• Drug Pricing
  • Possibly Bi-Partisan?
    • CREATE Act – give legal remedies to generic manufacturers that are blocked from obtaining samples
    • Preserve Access to Affordable Generics Act (pay for delay) – ban legal settlements over patent disputes from delaying the entry of generic drugs

• Drug Importation
• Affordable Care Act
• Reforms for Medicare Part D
• Opioids
Recent drug pricing legislation

**S. 2553: Know the Lowest Price Act**  
Sponsor: Sen. Debbie Stabenow (D-MI)  
- Prohibits a prescription drug plan under Medicare or Medicare Advantage from restricting a pharmacy from informing an enrollee or of any difference between the price, copayment, or coinsurance of a drug under the plan and a lower price of the drug without health-insurance coverage

**S. 2554: Patient Right to Know Drug Prices Act**  
Sponsor: Sen. Susan Collins (R-ME)  
- Ensures that health insurance issuers and group health plans do not prohibit pharmacy providers from providing certain information to enrollees so patients may know which drug option costs less  
- Bans the practice of pharmacy gag clauses under which a pharmacist may not inform customers if a prescription would cost less for a customer to pay cash for the prescriptions  
- Combats the estimated $135 million Americans overspend on prescriptions through their insurance

**H.R. 1892: Bipartisan Budget Act of 2018**  
Sponsor: Rep. John Larson (D-CT-1)  
- Closes the Medicare Part D coverage gap a year earlier than mandated by the ACA by increasing the manufacturer discount that goes towards beneficiaries’ out-of-pocket costs  
- Extends the Coverage Gap Discount Program to include biosimilar drugs

Sources: [www.Congress.gov](http://www.Congress.gov); National Journal
In October, APhA attended 3 bill signings in the White House:
• Patient Right to Know Drug Prices Act
• Know the Lowest Price Act
• SUPPORT for Patient and Communities Act

Image Source: White House
Legislation to Watch

**H.R. 275: Medicare Prescription Drug Price Negotiation Act of 2019**
Sponsor: Rep. Peter Welch (D-VT-At Large)
• Requires CMS to negotiate with pharmaceutical companies regarding prices for drugs covered under the Medicare prescription drug benefit
• Current law prohibits the CMS from negotiating

Sponsor: Sen. Bernie Sanders (I-VT) and Rep. Ro Khanna (D-CA-17)
• Aims to lower prescription drug prices by ending government-granted monopolies for manufacturers who charge higher drug prices in the United States than in other countries

**S. 61/H.R. 478: Safe and Affordable Drugs from Canada Act of 2019**
Sponsor: Sen. Chuck Grassley (R-IA) and Chellie Pingree (D-ME-1)
• Amends Chapter VIII of the Federal Food, Drug and Cosmetic Act by adding language that allows for the personal importation of drugs from approved pharmacies in Canada
• Prohibits purchasing from Canada for the purpose of resale and supplies over 90 days

Sources: [www.congress.gov](http://www.congress.gov); Paige Wulff | National Journal
Legislation to Watch

Sponsor: Sen. Leahy (D-VT) and Rep. Cicilline (D-RI)
- Promotes competition in the market for drugs and biological products by facilitating timely entry of lower-cost generics and biosimilars

**S. 205/ H.R. 937 Right Rebate Act of 2019**
Sponsor: Sen. Wyden (D-OR) and Rep. Schrader (D-OR)
- Requires drug manufacturers with Medicaid rebate agreements to disclose drug product information
- Manufacturers are subject to penalties for knowingly misclassifying drugs

**H.R. 803: Improving Transparency and Accuracy in Medicare Part D Spending Act**
Sponsor: Rep. Welch (VT)
- Prohibits Medicare plan sponsors from retroactively reducing payments on clean claims by pharmacies (e.g. DIR fees)

Sources: [www.congress.gov](http://www.congress.gov); Paige Wulff | National Journal
Bipartisan Collaboration on Senate Finance Committee

“This legislation is a significant step forward to fixing the problems in our health care system that have allowed pharmaceutical manufacturers to price gouge taxpayers and consumers for too long.”

- Senator Chuck Grassley (R-IA) on the Right Rebate Act of 2018, cosponsored with Senator Ron Wyden (D-OR)
Other Potential 2019 Health Care Agenda Items for Congress

**Introducing universal health care**

**Background**
- Many Democrats campaigned on different versions of “Medicare-for-all” during the 2018 midterms
- There is support for different forms of “Medicare-for-all” from many democrats
- Sen. Bernie Sanders (I-VT) and Rep. Pramila Jayapal (D-WA) have proposed “Medicare-for-all” bills
- Several others including Sen. Tim Kaine (D-VA) have proposed Medicare or Medicaid buy-in options

“\[This [Progressive] caucus is committed to not only making sure that every American across the country has quality, affordable health care but also holding the President accountable for making meaningful improvements to our healthcare system instead of continuing to promote policies that take healthcare away from people.\]”

— Pramila Jayapal (D-WA-7)

Sources: [www.congress.gov](http://www.congress.gov); Felicia Sonmez, “House votes to repeal medical device tax,” The Washington Post, July 24, 2018; Paige Wulff | National Journal

**Repealing the medical device tax**

**Background**
- Congress may reintroduce legislation that would repeal the 2.3% excise tax on medical devices sold by medical manufacturers
- The original bill, the Protect Medical Innovation Act of 2018 was introduced to the House on January 3, 2017 then passed the house on July 24, 2018
- The bill did not see any movement in the Senate
- The tax is currently set to take effect in 2020
Legislation to Watch: Health Care Reform

**H.R. 259: Medicaid Extenders Act of 2019**
Sponsor: Rep. Frank Pallone, Jr. (D-NJ-6)
- Makes appropriations for FY2019
- Reduces the federal medical assistance percentage for states that have not implemented asset-verification programs for determining Medicaid eligibility
- Reduces funding available to the Medicaid Improvement Fund beginning in FY2021

**H.R. 269: Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019**
Sponsor: Rep. Anna Eshoo (D-CA-18)
- Reauthorizes certain programs under the Public Health Service Act and the Federal Food, Drug, and Cosmetic Act with respect to public health security and all-hazards preparedness and response, to clarify the regulatory framework with respect to certain nonprescription drugs that are marketed without an approved drug application

**H.R. 525: Strengthening the Health Care Fraud Prevention Task Force Act of 2019**
Sponsor: Rep. Greg Walden (R-OR-2)
- Amends title XI of the Social Security Act to direct the Secretary of Health and Human Services to establish a public-private partnership for purposes of identifying health care waste, fraud, and abuse

Sources: [www.congress.gov](http://www.congress.gov); Paige Wulff | National Journal
Pharmacists’ Provider Status

Provider Status = Increasing patient access to/ coverage of quality, pharmacist-provided patient care services

(Services beyond those related to dispensing)
Pharmacists’ Provider Status in 115th Congress

Number of Cosponsors
H.R. 592 – 297 (173 Rs; 124 Ds)
S. 109 – 56 (25 Rs; 30 Ds)
Bipartisan
Pharmacists’ Provider Status

- New Congress requires any legislative proposal to be reintroduced
  - Congressional session = 2 years
- Patient Access to Pharmacists’ Care Coalition (PAPCC) currently discussing path forward in new Congress and with new leadership
  - Change of control in House and changes in committee chairs
- Legislation is just one of our members’ profession’s pathway to success
  - Federal agencies opportunities
    - Device approvals, opioids, clarifying and/or relaxing “incident to” requirements, medication management, Quality Payment Program (QPP) including MIPS, APMs, CCM, TCM, Annual Wellness Visits (AWV), Diabetes Self-Management (DSME)
- State-level and private sector efforts
Pharmacists’ Provider Status

Pathways to Achieve Provider Status

• Federal Sector
  • Legislative – E.g., Social Security Act for Medicare Part B & D
  • Regulatory – E.g., CMS and CMS Innovation grants (CMMI), SAMHSA, FDA

• State
  • Legislative and regulatory to affect Medicaid, Health Insurance Exchanges, state health plans, scope of practice, etc.

• Private Payer
  • Private or Employer-based Insurers
1. Which one of the following pieces of legislation was signed into law in 2018?

a. DQSA

b. Ensuring Seniors Access to Pharmacy Act

c. Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT for Patients and Communities Act)

d. Comprehensive Addiction and Recovery Act
2. Which beneficiaries would be eligible to receive services (and pharmacists eligible to receive reimbursement for these services) if the Pharmacy and Medically Underserved Areas Enhancement Act had passed and was signed into law?

a. All Medicare and Medicaid beneficiaries
b. Medicare beneficiaries who live in medically underserved communities
c. Only patients at federally qualified health centers
d. All Medicare patients
Assessment Question #3

3. What did Congress accomplish regarding drug pricing?
   a. Passed legislation to directly negotiate national prescription drug prices for Medicare (the same as the VA and DOD)
   b. Passed legislation allowing the federal government to import prescription drugs in shortage from other countries
   c. Passed legislation prohibiting PBM “gag clauses”
   d. Passed legislation removing the safe harbor for drug rebates across the federal government paid to insurance plans and PBMs
4. As of August 2019, which of the following will be true regarding hazardous waste pharmaceuticals?

a. In all states, healthcare facilities may not sewer hazardous waste pharmaceuticals

b. All states must adopt 40 CFR part 266 subpart P – Standards for the Management of Specific Hazardous Wastes and Specific Types of Hazardous Waste Management Facilities

c. All states must stop recognizing nicotine as an acute hazardous waste

d. Authorized states must adopt 40 CFR part 266 subpart P – Standards for the Management of Specific Hazardous Wastes and Specific Types of Hazardous Waste Management Facilities
??QUESTIONS??

- Michael Baxter
- Jenna Ventresca
- Alicia Kerry Mica