

CONGRESSIONAL AND REGULATORY OUTLOOK AND ACTIVITIES IMPACTING PHARMACY

JCPP member organization
Government Affairs Staff

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PHARMACY PROVIDER STATUS LEGISLATION

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POLITICAL PERSPECTIVE AND OUTLOOK

Karry LaViolette, NCPA

PROVIDER STATUS

115th Congress – Reintroduction of the *Pharmacy and Medically Underserved Areas Enhancement Act*

- Senate – S. 109 – 50 cosponsors
- House – H.R. 592 – 242 cosponsors

PAPCC GOVERNMENT AFFAIRS ACTIVITIES

- ▶ Continual discussions with committee staff/ leadership
- ▶ Meetings with the new administration
- ▶ Grassroots and Media Activities
 - ▶ Targeted Senators
 - ▶ Vulnerable House Members
- ▶ Question for the Record for HHS Secretary Nominee Alex Azar

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CONGRESS AND HEALTH CARE-RELATED ACTIVITIES

Chris Topoleski, ASHP

PAPCC NEXT STEPS

- ▶ Work with lead sponsors and committee leadership on next steps and timeline
- ▶ Upcoming PAPCC Organization Fly-Ins
 - ▶ ASHP – Student and New Practitioner Legislative Day – January 27
 - ▶ NACDS – RxImpact Day – March 7-8
 - ▶ APhA – Student Summer Leadership Institute – July 13
- ▶ Continue to build co-sponsor support/ utilize full coalition grassroots

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POTENTIAL HEALTH-RELATED LEGISLATION: JANUARY 2017

- ▶ ACA repeal/replace
- ▶ Medicaid reform
- ▶ Medicare “extenders”
- ▶ SCHIP reauthorization
- ▶ UFAs (PDUFA, GDUFA, BsUFA)
- ▶ Drug pricing bills

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LAWS PASSED BY JANUARY 15, 2018

- ☒ ACA repeal/replace
- ☒ Medicaid reform
- ☒ Medicare “extenders”
- ☒ SCHIP reauthorization
- ☒ UFAs (PDUFA, GDUFA, BsUFA)
- ☒ Drug pricing bills

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DRUG PRICING

- ▶ Surge in drug prices “old” drug is rebranded
- ▶ High launch prices
- ▶ Off patent drugs with no generic equivalent
- ▶ Misuse of REMS to manipulate the market
- ▶ Lack of competition in generic market
- ▶ Questionable patent arrangements

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WHAT HAPPENED?

- ▶ After 7 years of pushing for repeal, Republicans didn’t come to the table with a complete and agreed upon replacement to the ACA
- ▶ Consequently, 9 months of efforts to pass something, anything, to repeal the ACA
- ▶ One-sided bill, strategy was to rely only on Republican Senate votes all along – can only afford to lose 2 Senators

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DRUG PRICING LEGISLATION

- ▶ 30 bills introduced in House and Senate to date
- ▶ Bills fall under one or more of the following categories:
 - ▶ Importation
 - ▶ Direct Federal government negotiation
 - ▶ Fostering competition

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IMPORTATION AND PDUFA REAUTHORIZATION

- ▶ Senator Bernie Sanders (I-VT) had a potential amendment that would have allowed pharmacies, wholesalers and patients to import prescription drugs into the U.S. from Canada and other selected countries
- ▶ Ultimately only 3 amendments were attached to PDUFA and the importation amendment was not offered or discussed

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EDUCATION ISSUES

Jeffrey Ekoma, AACCP

POTENTIAL HEALTH LEGISLATION 2018

- ▶ ACA stabilization
- ▶ Medicaid reform
- ▶ Medicare "extenders"
- ▶ SCHIP reauthorization
- ▶ Drug pricing bills
- ▶ 340B Program

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PROSPER ACT (H.R. 4508)

- ▶ Promoting Real Opportunity, Success and Prosperity through Education Reform (PROSPER Act)
 - ▶ Reported out of committee (along party lines)
 - ▶ Legislative vehicle to reauthorize the Higher Education Act of 1965

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IMPLICATIONS FOR PHARMACY EDUCATION

- ▶ Elimination of all direct loan programs; transition to ONE loan program
- ▶ Elimination of graduate student eligibility for federal work study
- ▶ Elimination of GradPLUS
 - ▶ Graduate aggregate loan limits (per 9-month academic year) - **\$41,000**
 - ▶ Graduate aggregate loan limits (per 12-month academic year) - **\$45,167**
- ▶ Consolidation of loan repayment plans into two (2) income based repayment (IBR) plans
 - ▶ 10-year standard repayment
 - ▶ IBR capped at 15% of income
 - ▶ No loan forgiveness
- ▶ Repeal of Dept. of Ed. regulations on state authorizations

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AGENCY ISSUES AND UPDATE CMS, FDA, DEA

Soumi Saha, AMCP
Joan Baird, ASCP
Arnie Clayman, ASCP

WHATS NEXT?

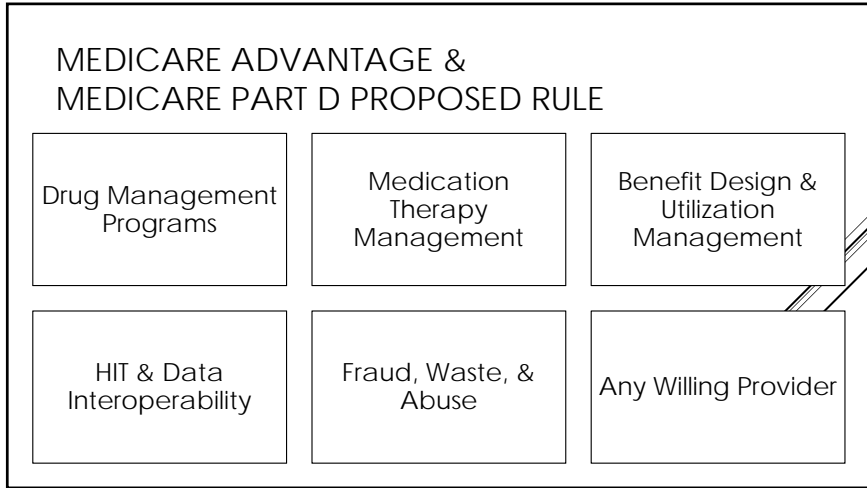
- ▶ Senate version slated for release early 2017
- ▶ No current plans on next steps in the House
- ▶ Joint letter from FASHP organizations to House Education and Workforce Committee
- ▶ AACP coordinating response to the Committee

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BIOSIMILARS

- ▶ FDA – Draft Interchangeability Guidance
- ▶ CMS – Medicare Part B Coding & Reimbursement
- ▶ State Activity

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- ▶ Medicare Conditions of Participation (SOM)
 - ▶ DRR/MRR recommendation & action documentation in patient medical record
 - ▶ Antibiotic Stewardship: systems to monitor use; antibiotic protocols
- THE "MEGARULE"
- 23

CMS – Reform of Requirements for Long-Term Care Facilities

THE "MEGARULE"

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- ▶ Medicare Conditions first published in 1989
 - ▶ Set standards for health care and safety
 - ▶ **First comprehensive update since 1991**
 - ▶ Proposed rule published July, 2015
 - ▶ CMS received nearly 10,000 comments
 - ▶ Final rule published October 4, 2016
 - ▶ **Phased Implementation**
 - ▶ Phase 1 – 11/28/2016
 - ▶ **Phase 2 – 11/28/2017**
 - ▶ Phase 3 – 11/28/2019
- THE "MEGARULE" – BACKGROUND INFO
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▶ **Phase 1 -**

- ▶ Documentation of DRR recommendations and prescriber response
- ▶ Updates definition of medication "irregularity"

▶ **Phase 2 -**

- ▶ Antibiotic Stewardship Program
- ▶ Re-defines "psychotropic drugs"
- ▶ PRN antipsychotic & psychotropic drug rules (14 days)
- ▶ "F-TAGS" RE-NUMBERED

THE "MEGARULE" – KEY PHARMACY CHANGES

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IMPACT ACT 2014

"IMPROVING MEDICARE POST-ACUTE CARE TRANSFORMATION ACT"

- Bipartisan bill passed on September 18, 2014 and signed into law by on October 6, 2014
- **Requires standardized patient assessment data across Post-Acute Care (PAC) settings to enable:**
 - Improvements in quality of care and outcomes
 - Comparisons of quality across PAC settings
 - Information exchange across PAC settings
 - Enhanced care transitions and coordinated care
 - Person-centered and goals-driven care planning and discharge planning

▶ **On 11/24/17, just prior to Phase 2 implementation, CMS released a memo to surveyors**

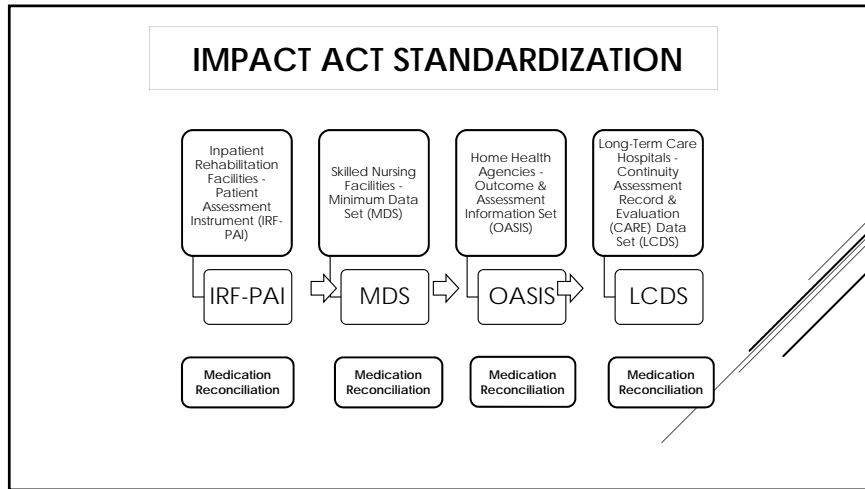
- ▶ An 18-month temporary moratorium on imposing enforcement remedies for certain Phase 2 requirements, including Behavioral Health Services (F740), Psychotropic Medications (F758), Antibiotic Stewardship Program (F881), as well as 5 other areas of care
- ▶ Health Inspection Star Ratings Frozen for one year

THE "MEGARULE" – **NEW**
DEVELOPMENTS

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IMPACT ACT 2014

- ▶ Standardized patient assessment data across all four PAC settings – Quality Measures Defined by CMS
- ▶ Defines PAC providers to include : **Home Health Agencies, LTACHs, SNFs and IRFs**
- ▶ Requires PAC providers to report standardized patient assessment data by October 2018
- ▶ Documentation of Medication Reconciliation at Admission & Discharge
- ▶ Communication of "Med Rec" to
 - ▶ Patient
 - ▶ Family
 - ▶ Primary Care Doc
 - ▶ Community Pharmacy



ASCP DEA TASK FORCE

- ▶ ASCP established its DEA Task Force in 1998 to address ambiguities within the CSA
 - ▶ Hospital vs. Community vs. LTC Pharmacy
 - ▶ CSA and the practice standards of LTCs represented a potential “regulatory compliance risk”
 - ▶ DEA Task Force - mission of working with the DEA to resolve issues and challenges - Balance patient care vs. regulatory compliance
 - ▶ Over the years, changes made to DEA regulations such as time required for follow-up written Rx for verbal CII orders and faxing of CII Rx’s

STANDARD DATA COLLECTION TIMELINE

Quality Domain	SNF Due Date
Functional Status	October 2016
Skin Integrity	October 2016
Medication Reconciliation	October 2018
Major Falls	October 2016
Patient Preference	October 2018

ASCP- DEA TASK FORCE UPDATE

Task Force – working directly with DEA staff since 2015 on list of issues, focused on Nurse Agency issue.

Issues Resolved:

Obtained written clarification from DEA:

- ▶ Electronic e-kits: use for 1st dose only **do not** require separate DEA registration (11/30/16).

Comprehensive Addiction & Recovery Act (CARA)

- ▶ DEA Clarification: CARA 30-day fill limitation **does not** apply to long-term care and hospice patients (1/13/17)
 - ▶ DEA verified, partial-fills for CII prescription medications with up to 60-days to complete.

CURRENT NURSE AGENT OVERVIEW

- ▶ **Authority of Agent (under current DEA guidance)**
 - ▶ Prepare CII-CV prescription for practitioner to sign
 - ▶ Transmit CII-CV prescription that is signed by practitioner to pharmacy via fax
 - ▶ Take a verbal CIII-CV prescription from the physician and communicate that prescription via telephone to the pharmacy
- ▶ **Agents are employed by the authorized prescriber and may be:**
 - ▶ A nurse located in the prescribers office
 - ▶ A non-licensed receptionist
 - ▶ Hospital employees (b/c hospitals are DEA registrants)
 - ▶ **NOT** LTCF Nurses for CDS. Nurses in a facility today remain the agent of the prescriber for non-controlled medications

CURRENT NURSE AGENT OVERVIEW

- ▶ October 6, 2010 DEA issues Policy Statement that addressed the nurse as an agent of the prescriber
- ▶ LTCF employees may become agents but only through a very prescriptive and detailed process that documents such delegation
- ▶ Each Nurse must be contracted with each prescriber and the pharmacy and the facility must maintain records of all contracts
- ▶ ASCP DEA-TF Recommended that DEA issue a revised Nurse Agent Policy which specifically addresses an alternative policy approach for the LTC setting
- ▶ Continued meetings with DEA in 2018 (Chart Orders, etc)