2015 Legislative Update: Critical Issues for Small and Rural Hospitals

Diane Calmus, J.D.
Government Affairs and Policy Manager
National Rural Health Association

Joseph Hill, M.A.
Assistant Director, Government Affairs Director, Federal Legislative Affairs
ASHP
Learning Objectives

• Discuss upcoming national legislation that will impact small and rural hospitals.
• Discuss legislative efforts to achieve pharmacist provider status under the Medicare program.
• Identify the challenges with implementation of the new prescription drug track and trace law, the Drug Supply Chain Security Act, and ongoing discussions with FDA.
• Describe efforts to change the 340B Drug Pricing Program.
Disclosure

Faculty, planner, ASHP staff and consultants report no relevant financial relationships pertinent to this activity.
What is a top priority of focus for your facility this coming year? (Choose one)

1. Patient safety
2. Improving quality and patient outcomes
3. Workforce training (such as computer systems or professional education)
4. Financial (such as control expenses or improve revenue)
Improving the health of the 62 million who call rural America home.

NRHA is non-profit and non-partisan.
Rural Overview

- 62 million patients rely on rural providers.
  - Population challenges
  - Geographic challenges
  - Cultural challenges
- Rural providers face health care delivery challenges like no other provider.
  - Workforce shortages
  - Fiscal constraints
- Rural providers and patients are disproportionately dependent on Federal Government.
  - Medicare and Medicaid
  - Appropriations
  - Regulatory Process
- Now, rural providers face unprecedented challenges from Washington, D.C.
A Rural Hospital Closure Crisis

- 55 Rural Hospitals have closed since January 2010
- 283 Rural Hospitals Vulnerable
Impact of 283 Hospital Closures

- 700,000 Patient Encounters
- 36,000 Healthcare Jobs Lost
- 50,000 Community Jobs Lost
- $10.6 Billion Loss to GDP

Source: Hospital Strength Index - Vulnerability Index

Powered by iVantage Health Analytics
It’s about the patients...

“Only four days after the Pungo District Hospital in Belhaven closed its doors for good on July 1, Portia Gibbs, 48, suffered a heart attack and died just as the chopper arrived to airlift her to a hospital. (Nearest hospital is now 75 miles away.)

“Before, she would have been given nitroglycerin, put in the back of an ambulance and been to a hospital in about 25 minutes,” said Belhaven Mayor Adam O’Neal. “In that hour that she lived, she would have received 35 minutes of emergency room care, and she very well could have survived.”

- Belhaven Mayor Adam O’Neal.

“[It] ends up with rural communities, such as Hancock County (Georgia), where 39 percent of the folks who have a stroke or have a heart attack die. That’s a lot higher than in counties with hospitals close by.”

David Lucas, Georgia State Senator.
It’s about access to care...

- 5,700 hospitals in the country; only 35 percent are located in rural areas.
- 640 counties across the country **without** quick access to an acute-care hospital.
- 60% of trauma deaths occur in rural America; though only 20% of Americans live in rural areas.
- Rural patients travel twice as far as urban counterparts to receive emergency care.
- “Access to care remains the number one concern in rural health care.” Rural Healthy People
Why are Rural Hospitals Closing?

1. MDH Expiration — 10% Cut to 200 Rural Hospitals
2. LVH Expiration — 13% Inpatient Cut to 650 Rural Hospitals
3. Sequestration — 2% Cut to All Rural Hospitals
4. 25% Cut in DSH Payments to Rural Hospitals (Non-CAH)
5. Hold Harmless — 4% Cut in Outpatient Payments
6. 35% Cut Uncompensated Care to Rural Hospitals
7. Coding and Documentation Cuts

THE BOTTOM LINE: 35%* of RURAL HOSPITALS OPERATING AT LOSS

*69% of Rural Hospitals have negative OPERATING profit margin
Advocacy

CHARTING A NEW COURSE
NRHAs Navigation for 2015!

Our Campaign:

1. Stop the bleeding. Halt additional proposed cuts to rural hospitals from the Administration and Congress immediately. Support pro-rural provisions such as Medicaid expansion, elimination of the 2% sequestration cuts and 101% reimbursement for CAHs to stabilize the rural safety net.

2. Build bridge to the future. Promote new provider payment models to create a new rural reality.

#SaveRural
The Save Rural Hospitals Act

Rural hospital stabilization (Stop the bleeding)

- Elimination of Medicare Sequestration for rural hospitals;
- Reversal of all “bad debt” reimbursement cuts;
- Permanent extension of Low-Volume and Medicare Dependent Hospital payment;
- Reinstatement of Sole Community Hospital “Hold Harmless” payments;
- Extension of Medicaid primary care payments;
- Elimination of Medicare and Medicaid DSH payment reductions;
- Establishment of Meaningful Use support payments for rural facilities struggling; and
- Permanent extension of the rural ambulance and super-rural ambulance payment.

Rural Medicare beneficiary equity. Uniform urban/rural out-of-pocket charges

Regulatory Relief

- Elimination of the CAH 96-Hour Condition of Payment;
- Rebase supervision requirements for outpatient therapy services at CAHs and rural PPS;
- Modification to 2-Midnight Rule and RAC audit and appeals process.

Future of rural health care (Bridge to the Future)

- Innovation model for rural hospitals who continue to struggle.
- Support for moving to value based payment and population health
Future Model: Community Outpatient Hospital

- 24/7 Emergency Services
- Meeting the needs of rural communities. Additional service based on community needs assessment: observation care, skilled nursing facility (SNF) care, infusion services, hemodialysis, home health, hospice, nursing home care, population health and telemedicine services.
- Primary Care – FQHC (or look alike) or Rural Health Clinic
Helping Rural Hospitals transition into the future

- Telehealth
  - Tele-emergency
  - Surveyor guidelines
  - Expanded services in PFS 2015
- Expand primary-care
- Community health needs assessment

- Health risk assessments
- EHR optimization
- Value-based Assessment in CAHs
- Bundled Payments
- ACOs
Focus on Efficiency

• Eliminate waste (lean)
• Flatten organizational structure
• Utilize all staff
• Aggressively review “bricks and mortar” budgets
Population Health

• Patient centered medical homes (PCMH)
• Decision support
• Mapping
• Interventions: population as patient
Congressional Budget FY16

• We have a budget!
  • $5 Trillion of cuts over the next decade – no detail
  • Both resolutions have the $1.016 trillion base discretionary spending level set in the 2011 debt limit law – lawmakers looking for a deal to lift sequester in conference
  • Includes a repeal of the Affordable Care Act

• What does this mean?
Appropriations

• Regular Order: 12 spending bills – For each chamber (subcommittee, full committee, floor consideration), conference committees, and Presidential signature
  • President issued Veto blanket threat (MilCon/VA expected first)

• Process is moving forward
  • 6 passed House – 4 approved by committee – 2 in subcommittee
  • 9 approved by committee – 3 in subcommittee – none on floor
  • Grumbling over restrictive spending levels and a number of controversial policy riders.
  • Time consuming process – bills generally considered in open amendment process
Medication-related Issues for Small and Rural Hospitals

Joseph Hill, M.A.
Assistant Director, Government Affairs,
Director, Federal Legislative Affairs
ASHP
Objectives

- Quick summary of dispenser requirements under the DSCSA (track and trace)
- ASHP activity/communication with FDA
- Unresolved issues, including 340B contract pharmacy
- Provider status update, plan for August recess
DSCSA Requirements for Dispensers

- Shall not accept ownership of a product from a distributor without:
  - Transaction information, history, statement (3Ts)
- Must provide subsequent owner with 3Ts unless exempted
- Must keep records of 3T collection for 6 years
- Must have systems in place to track, quarantine, investigate, retain samples, clear, notify others and dispose of suspect product
Exemptions

- Intracompany distribution of any product between members of an affiliate or within a manufacturer.
- Distribution of product between hospitals or healthcare entities under common control.
- Distribution of product for emergency medical reasons, which includes a public health emergency, and excludes a drug shortage unless caused by such a public health emergency.
- Distribution of minimal quantities by a licensed retail pharmacy or licensed practitioner for office use.
- Distribution of intravenous product intended for fluid and electrolyte replenishment (e.g., sodium, chloride, potassium) or calories (e.g., dextrose and amino acids).
- Distribution of intravenous product used to maintain equilibrium of water and minerals in body (e.g., dialysis solution).
- Product intended for irrigation or sterile water.
- Distribution of medical gas.
- Drugs compounded in compliance with section 503A or 503B.
Exemption for 340B Ship to/Bill to Contract Pharmacy Arrangements

Request that the FDA:

1) **Exempt** Wholesale Distributors from sending the TI/TH/TS to the 340B Covered Entity Purchasing the Drug Product; and,

2) **Instead**, require Wholesale Distributors to send *both* the TI/TH/TS and the Drug Products Solely to the Contract Pharmacy; and,
340B and Contract Pharmacy

- Late 2014 a coalition formed around the issue: ASHP, NACDS, 340B Health, NCPA, Walgreens
- Have met with FDA numerous times regarding this issue
- FDA is reportedly working on a fix
Track and Trace

- June 1: FDA held listening session for dispensers
  - ASHP, APhA, NCPA, NACDS, NASPA participated
- Two ASHP members pointed out unresolved issues, questions around compliance
Unresolved

- Borrow and loan, emergent use exempted, but what about first responders (naloxone)?
- Upstream readiness, mixed communication
- Processes to verify product, every product? Just a sample?
- Portal based system, questions remain with contracts, written agreements
- Other, questions about certain drugs
Track and Trace

- June 16: ASHP submitted formal request to FDA for enforcement discretion beyond the July 1 deadline.
  - Cited member concerns, unanswered questions
- June 30: FDA issued enforcement discretion for dispensers until **November 1, 2015**
Track and Trace

ASHP will continue engaging FDA, providing member feedback, working on unresolved issues.

ASHP Web Resource: [www.ashp.org/dscsa](http://www.ashp.org/dscsa)
Audience Polling Question

Are you aware of legislation that would list pharmacists as providers in the Medicare program, H.R. 592?

1. Yes
2. No
Audience Polling Question

Are you aware of legislation that would list pharmacists as providers in the Medicare program, S. 314?

1. Yes
2. No
Provider Status

- Latest status of the bills
- Where we are lacking in terms of support
- ASHP’s plan to increase member contact with lawmakers over the August recess
- We need help from ASHP state affiliates and NRHA members
Provider Status

To date, roughly 2,500 letters sent in support of the bills

- Largely through our electronic letter writing platform
- This number needs to increase

Active ASHP members are challenged to engage their colleagues
June 25, 2015

The Honorable Angus King
United States Senate
Hart Senate Office Building, Room: 133
2nd and C Streets, N.E.
Washington, DC 20510

Dear Senator King,

As a constituent and a pharmacy leader for our state, I am writing to encourage you to cosponsor the Pharmacy and Medically Underserved Areas Enhancement Act (S. 314), a bill that would enable pharmacists to provide essential patient care services to Medicare beneficiaries in medically underserved areas.

As the Director of Pharmacy for Penobscot Community Health Care, Maine's largest Federally Qualified Health Center, I have had the privilege of leading efforts to improve access, safety, and quality of health care through the integration of pharmacists into the primary care team. As medication experts, pharmacists possess a unique and complimentary skill set in the area of medication use, and can work collaboratively with physicians and other health care providers to help Medicare beneficiaries achieve optimal health outcomes.

In my role, I have been able to work with many other health-systems, hospitals, and health centers seeking to improve patient care through the integration of pharmacists into the care team. There is great desire within the organizations in Maine to leverage the skills of the pharmacist to close gaps in care. The challenge is how to best accommodate the cost of additional staff under the constraints of current payment models. To grow the quality of health care, each member of the team is needed to play their part and the passage of S. 314 will support this.

This bill will make a tremendous difference to patients needing additional access to the essential health care services that pharmacists provide in collaboration with other members of the health care team. S. 314 will allow our pharmacists to work within state laws that govern pharmacy practice to be a more effective member of the team as we work together to care for our patients.
Provider Status

Action Plan Going Forward

✓ PAPCC continues with group Hill visits
✓ September—ASHP legislative day
  ✓ 100 members on the Hill, high impact
✓ October—National pharmacists month
  ✓ Health fair on the Hill
✓ Fall 2015—Congressional hearing on the bills? Potentially
Provider Status

Could the bills move in the fall?
- Potentially, much of Congressional agenda is out of our hands, but we won’t be successful if we’re not putting pressure on them, a hearing could be possible

2016
- The farther along we get in 2016, the more the focus will be on the Presidential election

Sense of urgency
- The time to act is now!
August Recess Plans

- Congress is back home 2nd week of August through 1st week of September
- ASHP e-mailed all 535 members asking about dates/times/locations of town hall events
  - These are meetings where Congress hears directly from constituents
August Recess, continued

- If town hall meeting information is not available, set up a meeting in the district/state.

- Similar to a Hill meeting, likely with staff, however if the member is around they may introduce themselves to you.
August Recess, continued

- ASHP will collect the town hall information, push it out to state affiliates
- Urging affiliates to attend one or two of the events, bring colleagues, make it a group outing
- Talk about the importance of the legislation: access to care, value of pharmacists provided care
August Recess, continued

Not hard to set up

- Greater San Francisco Bay group recently met with Senator Boxer’s office, she’s now on the bill
- Similar meeting in Texas earlier this year

Our resources:

- www.ASHP.org
Critical States

- PA - Senator Toomey
- KS - Senator Roberts
- OR - Senator Wyden
- ID - Senator Crapo
- TX - Senator Cornyn
- TN - Senator Alexander
- UT - Senator Hatch
Districts where this is critical

- NJ District 6 - Rep. Pallone (Ranking member E & C)
- MI District 6 - Rep. Upton (Chair E & C)
- CO District 1 - Rep. DeGette
- MD District 5 - Rep. Hoyer (leadership)
- OR District 2 - Rep. Walden
- PA District 16 - Rep. Pitts (Chair Health Sub)
Others

States where access to care is a challenge:
- Maine
- Dakotas
- Wyoming
- Montana
- Utah

Others: OH Senator Portman, SD Senator rounds, WI Senator Johnson
Increasing scrutiny of the program
Recent GAO report claiming higher Part B spend for DSH hospitals—ASHP takes issue
On the lookout for efforts to dismantle the program
Tell your story of 340B and why the program is critical
2015 Legislative Update: Critical Issues for Small and Rural Hospitals

Questions and Answers

Diane Calmus, J.D.
Government Affairs and Policy Manager
National Rural Health Association

Joseph Hill, M.A.
Assistant Director, Government Affairs
Director, Federal Legislative Affairs
ASHP