LEGISLATIVE AND REGULATORY UPDATES

PHILLIP PORTE

EXECUTIVE DIRECTOR
NAMDRC

Phillip Porte was born and raised in Chicago, Illinois and completed his undergraduate degree at the University of Wisconsin with a Bachelors Degree in English and a minor in Political Science (1970).

After a relatively short stint with City New Bureau, CBS News, and St. Mary of Nazareth Hospital Center, all in Chicago, he arrived in Washington, DC in 1976 to work at the National Health Policy Forum, a foundation funded program that runs educational seminars for Federal health policymakers. While going to graduate school at the George Washington University in the Masters Program for Public Administration, he immersed himself in the nuances of national health policy. In 1978 he opened his own health care consulting and lobbying firm, representing the American Association for Respiratory Care. In the 31 years since, GRQ has established a strong reputation in the field of pulmonary medicine, representing NAMDRC as well as other pulmonary medicine societies, device manufacturers, pharmaceutical companies, and providers of hospital, nursing home and home care.

He has published articles in numerous journals relating to pulmonary medicine coverage and payment issues and has served as Executive Director of NAMDRC, a client of GRQ since 1979, for approximately 17 years.

OBJECTIVES:

Participants should be better able to:

- Understand the impact of Legislative & Regulatory activities on their practice of Pulmonary Medicine

FRIDAY, MARCH 23, 2018 11:45 AM

NAMDRC Annual Educational Conference

Legislative & Regulatory Issues

No Conflicts of Interest Related to this Presentation

A Brave (?) New World

- 2nd HHS Secretary
- CMS Administrator, hand picked by Vice President Pence, comes from Medicaid (Indiana) background with little Medicare experience
- Affordable Care Act???
- Eliminate at least two existing regulations for every new one
- Return to bundling models

Issues Du Jour/Week/Month/Years

- Home Mechanical ventilation
  - Direct involvement kicked into very high gear 2014
- Pulmonary Rehab
  - 1981 letter opens door for local policies
  - 2008 legislation formalizes coverage
- Oxygen
  - Since beginning of time
- Bundling Issues
- Pharma Issues

Home Mechanical Ventilation

- CMS Administrator writes to Capitol Hill

The Coverage & Analysis Group is undertaking a complete review of the clinical evidence. After reviewing the white paper [developed by NAMDRC] and speaking with several respiratory groups of stakeholders as well as reviewing the literature provided by them, CAG began the work necessary to perform a comprehensive lliterature review…."

HMV (continued)

- One week prior to the date of that letter AHRQ, under contract with Mayo Clinic, sought formal input with 30 day deadline.
- NAMDRC, CHEST/ACCP and AARC responded in joint statement…
- Reiteration of previous statements
- February 2018 AHRQ begins another literature review, again with one month deadline.
- NAMDRC submits all previous info previously provided to CMS, none of which AHRQ had seen or were aware of.
- Drs. Gay, Hill, Wolfe and Lamberti meet with AHRQ to address their questions, paucity of RCTs, importance of observational studies,

HMV (cont'd)

- Agreement reached for additional submission, followed by review of AHRQ draft currently anticipated in June.
- Legislative language being drafted after 4 year effort with CMS
  - Defining "respiratory failure" with sunset provision to reflect medical advances
  - Use of ventilator is appropriate treatment for respiratory failure
  - RF is not a constant, and need can appear intermittently, nocturnally, and need for continuous use.
  - CMS acknowledgement of FDA classifications to eliminate RAD verbiage.
  - Not related to treatment of OSA.

Pulmonary Rehab

- AACVPR undertakes massive outreach to 600+ hospitals with documented low charges and relatively high number of claims
- Fewer than 50 even responded to two attempts at outreach
- Poor payment here to stay, unfortunately for foreseeable future.
- BUT IT GETS WORSE
- Site of service regulations crippling pulmonary rehab.
- Legislative initiative is only solution.
- ACCESS ACT does permit NPPs to supervise PR, effective 2024.

Pulmonary Rehab

- TV time on CBS Sunday Morning with great story with Ted Koppel
- We worked with producer of show for several weeks prior to airing
- One key takeaway: NIH acknowledges COPD ranks 155th in funding levels.

High Flow Oxygen Therapy

- Patients requiring 4L+> struggle outside of home
- Pulmonary fibrosis patients particularly impacted
- Key societies meeting next month to explore legislative options
- Competitive bidding has killed access to liquid systems, perhaps only viable approach to offer continuous outside of home.

CMS Innovation Center (CMMI)

- Quality Payment Program has two tracks:
  - Advanced Alternative Payment Models (APMs)
  - Merit-based Incentive Payment System (MIPS)
- Voluntary episode payment models (2013)
- Stated Goal:

  to test models that improve care, lower costs, and better align payment systems to support patient-centered practices

https://innovation.cms.gov/About/index.html

Bundled Payment Care Improvement BPCI

32 clinical episodes, including:

- Chronic obstructive pulmonary disease
- Bronchitis and asthma
- Pleural effusion
- Pulmonary edema and respiratory failure
- Respiratory system diagnosis with ventilator support 96+ hours
- Respiratory system diagnosis with ventilator support <96 hours

Bundled Payments for Care Improvement Advanced (BPCI-A)

- New version of total-cost-of-care concept
- Fee-for-Service (FFS) beneficiaries
- 90-day episode bundled payment based on “target price”
- Acute care hospitals & physician group practices
- Payment is tied to performance on quality measures

https://innovation.cms.gov/initiatives/bpci-advanced

BPCI-A Episodes

- 29 inpatient & 3 outpatientt clinical episodes
- Includes:
  - Simple pneumonia & respiratory infections
  - COPD, bronchitis, asthma
- Qualifies as an Advanced Alternative Payment Model (APM)
  - Qualified participants eligible for 5% bonus in payment yrs 2019-2024
- Current model begins Oct 1, 2018 through Dec 31, 2023
- Next enrollment period January, 2020

CMMI Quality Measures

Two measures applied to all episodes:

- All-cause Hospital Readmission Measure (NQF #1789)
- Advanced Care Plan (NQF #0326)
- Other measures are episode specific

Disfu

"My desire to be well-informed is currently at odds with my desire to remain sane."

Congressional Health Care Agenda

- 340B
  - Exponential program growth ($8.8 billion in sales in 2014; $16.2 billion in 2017). Half of all hospitals are now covered entities, up from 34% in 2014
  - Increased Congressional oversight/hearings
  - Final rule ASP - 22.5% (lawsuit pending)
- Scrutiny of mega mergers (CVS-Aetna; Cigna-Express Scripts)
- Opioids- CARA 2.0
- Drug Pricing
- Increasing activity at the state level on pricing, transparency, Medicaid expansion/waivers

Drug Pricing

- Continued drumbeat on drug prices although unlikely to see much progress
- New focus on all actors in the drug supply chain (manufacturers, distributors, PBMs, insurers)
- Recent White House drug pricing proposals:
  - Reducing Part B reimbursement to ASP +3% for newly launched drugs
  - Requiring 340B savings either go to hospitals that are delivering adequate amount of uncompensated charity care or return to the trust fund
  - Allowing up to 5 states to "negotiate" prices in Medicaid
  - Moving Part B drugs to Part D
- Longer term debate about changing market structure and how to pay for new generation of medicine (immunotherapy/CAR-T, gene therapy)

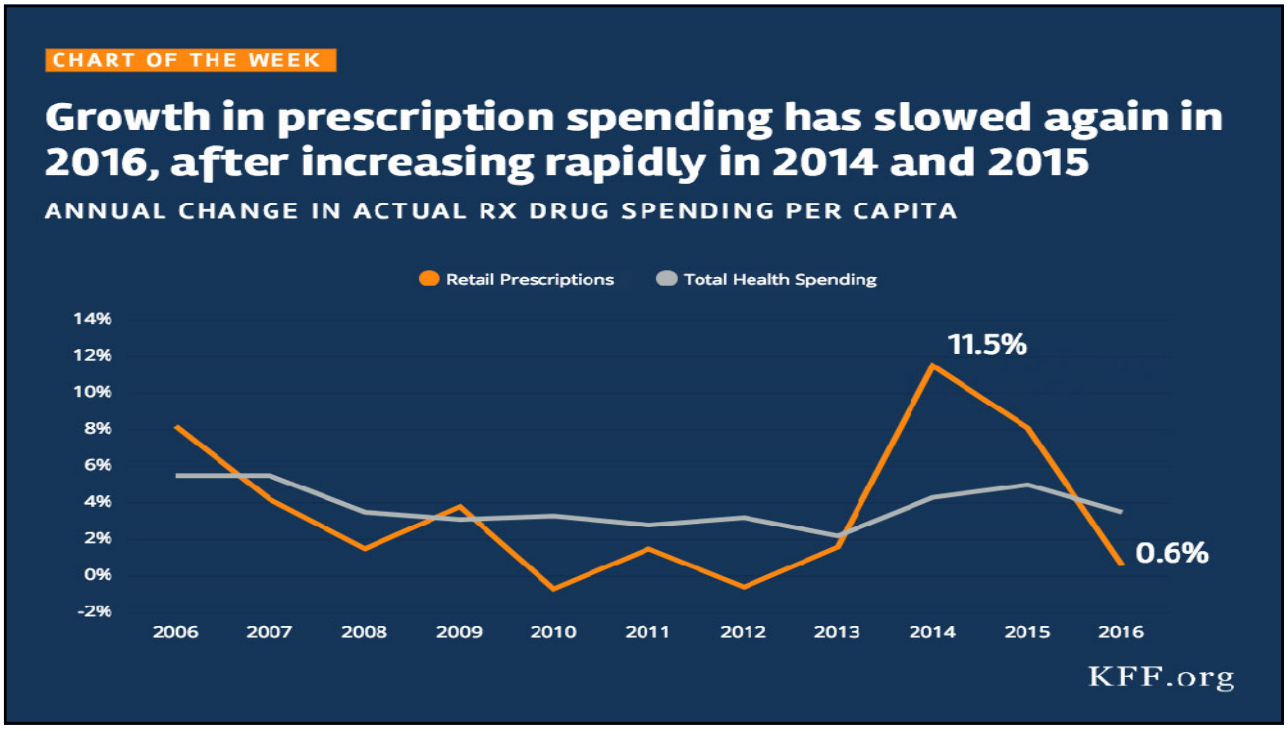
CHART OF THE WEEK
Growth in prescription spending has slowed again in 2016, after increasing rapidly in 2014 and 2015
ANNUAL CHANGE IN ACTUAL RX DRUG SPENDING PER CAPITA
Retail Prescriptions
Total Health Spending
14%
12%
10%
8%
6%
4%
2%
0%
-2%
11.5%
0.6%
2006
2007
2008
2009
2010
2011
2012
2013
2014
2015
2016
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