GOVERNMENT PRICING PROGRAMS:

KEY ISSUES FOR COMPLIANCE PROFESSIONALS

Wendy C. Goldstein

March 21, 2016

AGENDA

I. Environment

II. Key Compliance Considerations

I. ENVIRONMENT

SIGNIFICANT MEDIA ATTENTION

Cooley LLP

CNN

'Outrageous' pill prices are big business as usual

The Washington Post

How an obscure drug's 4,000% price increase might finally spur action on soaring health-care costs

The New York Times

Valeant's Drug Price Strategy Enriches It, but Infuriates Patients and Lawmakers

THE WALL STREET JOURNAL.

Pharmaceutical Companies Buy Rivals' Drugs, Then Jack Up the Pric

SIDE EFFECTS PUBLIC MEDIA

Sanders, Cummings Announce Bill To Rein In Prescription Drug Prices

The New York Times

Drug Goes From $13.50 a Tablet to $750, Overnight

USA TODAY

Turing pharma CEO recedes from public after backtracking on drug price hike

THE WALL STREET JOURNAL.

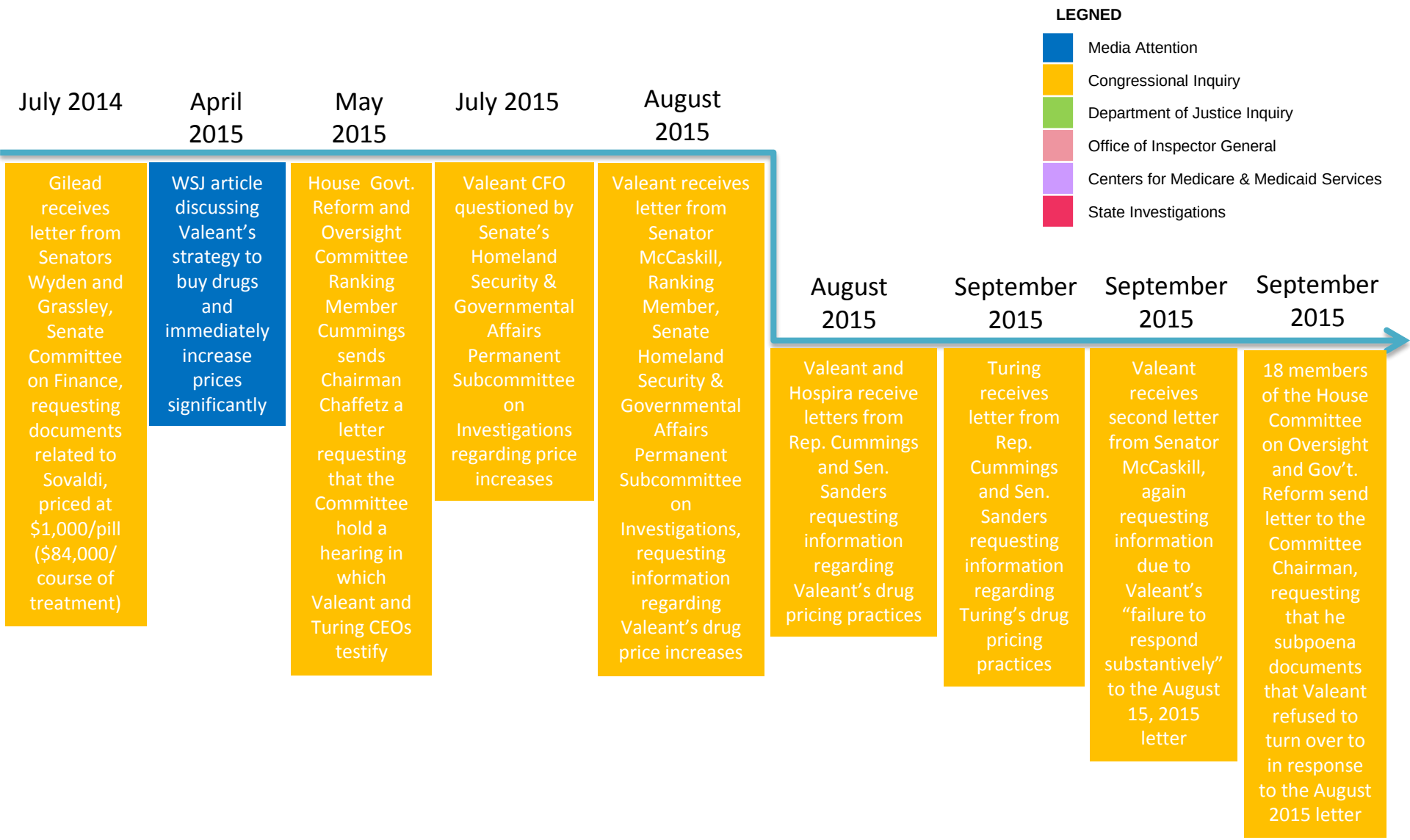
Lilly, Merck and Valeant Receive Inquiries About Drug Pricing

Forbes

Turing's Drug Price Gouging Gives Politicians A Gift And Biotech A Perhaps Enduring Headache

DRUG PRICING INQUIRY TIMELINE

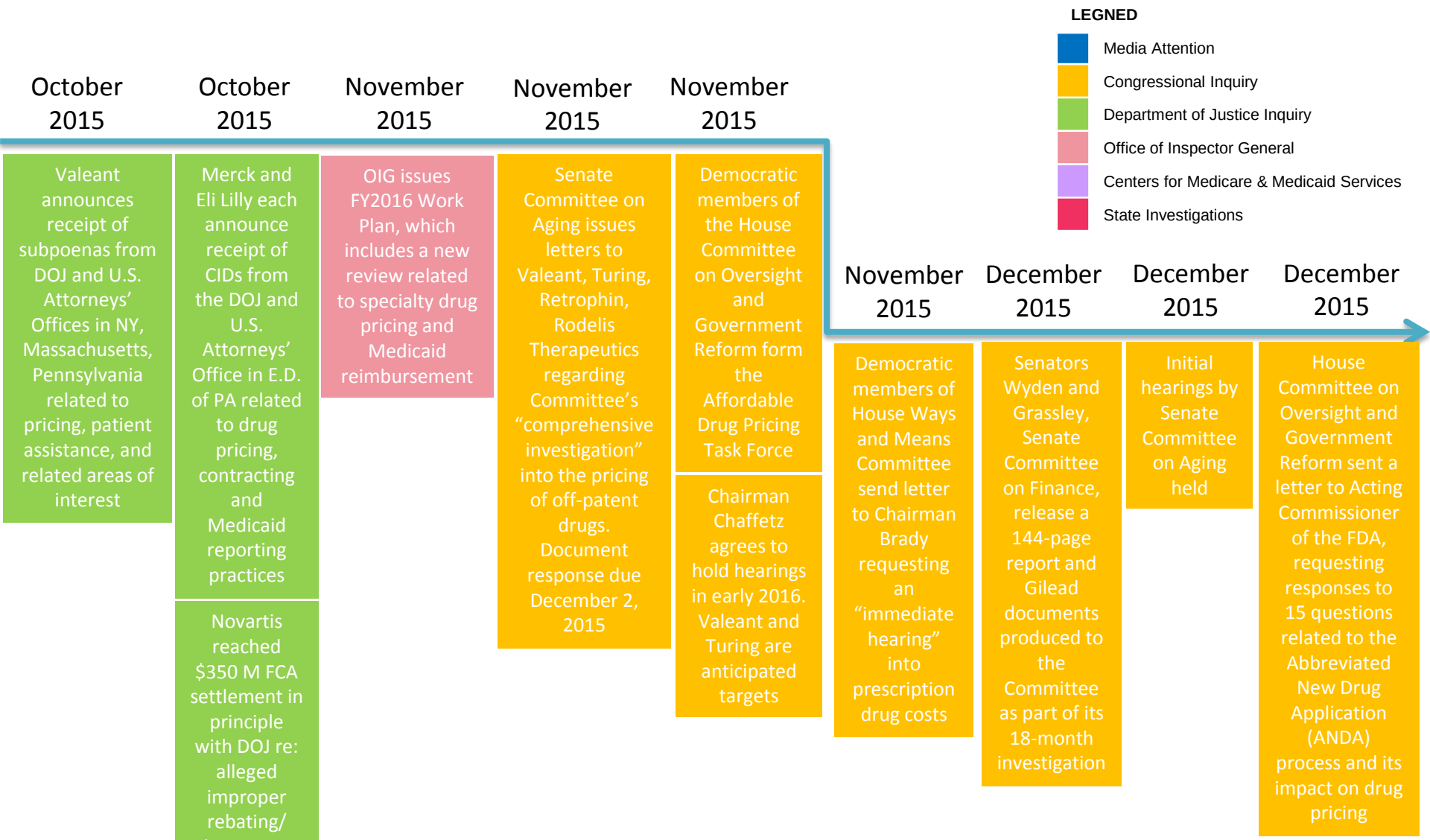
Cooley LLP



** All content is based on public information only*

DRUG PRICING INQUIRY TIMELINE (CONT.)

Cooley LLP



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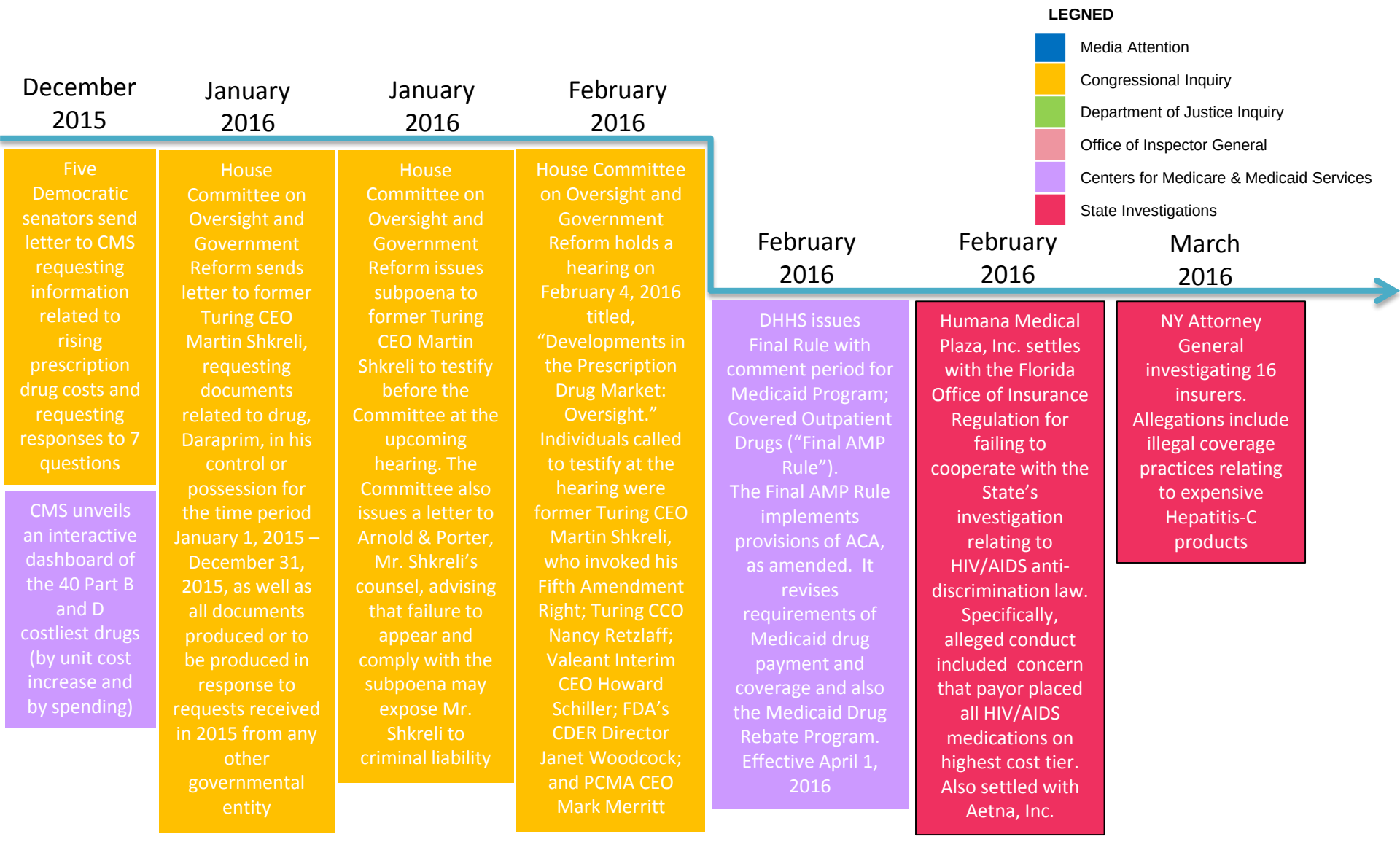

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AREAS OF CONGRESSIONAL FOCUS

Cooley LLP

- Senate Finance Committee
  - "Senators Wyden and Grassley have raised the following policy questions for public debate, with the goal of improving wider access to effective and affordable drug treatments"
    1) What are the effects of a breakthrough, single source innovator drug on the marketplace?
    2) Do the payers in the programs have adequate information to know the cost, patient volume, and increases in efficacy of a new treatment regimen?
    3) What role does the concept of "value" play into this debate, and how should an innovative therapy's value be represented in its price?
    4) What measures might improve price transparency for new higher-cost therapies while maintaining incentives for manufacturers to invest in new drug development?
    5) What tools exist, or should exist, to address the impact of high cost drugs and corresponding access restrictions, particularly on low-income populations and state Medicaid programs?

AREAS OF CONGRESSIONAL FOCUS

- Senate Committee on Aging
  - Substantial price increases on recently acquired off-patent drugs
  - Mergers and acquisitions within the pharmaceutical industry that have sometimes led to dramatic price increases for off-patent drugs
  - FDA's role in the drug approval process for generic drugs, FDA's distribution protocols, and off-label regulatory regime

POLITICAL FOCUS

- Presidential candidates also jumping on the drug pricing bandwagon. Dem. Candidate Hillary Clinton's plan to lower drug prices includes:
  - "Eliminate corporate write-offs for direct-to-consumer advertising"
  - "Establish a mandatory FDA pre-clearance procedure for these [DTC] ads funded through user-fees paid for by pharmaceutical manufacturers"
  - "Require health insurance plans to place a monthly limit of $250 on covered out-of-pocket prescription drug costs for individuals"
  - Lower "the biologic exclusivity period from 12 to 7 years"
  - "Require drug manufacturers to provide rebates for low-income Medicare enrollees"
  - "Allow Medicare to negotiate drug and biologic prices"
- Presidential candidate Rep. Donald Trump supports importation and direct price negotiation

LEGISLATION/REGULATIONS

- Legislation introduced in several states (CA, MA, NY, NC, OR, PA) that would require pharmaceutical manufacturers to submit reports to the state outlining the total cost of drug production, including marketing costs
  - The recently repealed California legislation would require "… each manufacturer of a prescription drug made available in [CA], that has a [WAC] of $10,000 or more annually or per course of treatment to file a report, no later than May 1 of each year, with the Office of Statewide Health Planning and Development on the costs for each qualifying drug…. the [Office] issues a report annually and posts on the [Web]. … Confidentiality provisions taken into consideration."
- On March 8, 2016, CMS issued a proposed rule for comment, to test Medicare Part B payment methodologies for five years
  - Includes different prescriber and pt. incentives designed to drive effective prescribing and reward positive pt. outcomes

INDUSTRY OUTLOOK

- Companies lowering prices
- Value-based purchasing/ “risk-sharing” arrangements
- Federal and state legislation
- Outcome of congressional inquiries
- Outcome of DOJ investigations
- State AG payor investigations

II. KEY COMPLIANCE CONSIDERATIONS –

What does this environment mean for Compliance Professionals?

RAMIFICATIONS FOR COMPLIANCE

- Policies, procedures, training, auditing and monitoring activities must be updated to address developments in pricing as well as the environment
  - Directors, officers, management
  - Key departments and committees
    - Government Pricing (GP) Department
      - Final AMP Rule Implementation
    - Pricing Committee
      - Pricing proposals, rebate structures, risk-based contracting/ value-based proposals
      - Return policies
    - Reimbursement Support Department

RAMIFICATIONS FOR COMPLIANCE

- Key Activities for training, monitoring, auditing
  - Reimbursement Support
  - Trade /Distribution channels
  - Patient assistance programs
  - Copay mitigation programs
  - Patient compliance, adherence and persistency programs
  - Sampling programs
  - Documentation

RAMIFICATIONS FOR COMPLIANCE

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- Key Compliance Principles
  1. "Integrity of data used by state and federal governments to establish payment amounts" OIG Compliance Guidance
     - GP Function - King Pharmaceuticals Settlement (2005)
     - Manufacturer certifications in GP
       - Medicare ASP (quarterly) - CEO, CFO, or Authorizing Official certifies that "the reported Average Sales Prices were calculated accurately and that all information and statements made in this submission are true, complete, and current to the best of my knowledge and belief and are made in good faith. I understand that the information contained in this submission may be used for Medicare reimbursement purposes."
       - Medicaid Drug Rebate Reports (monthly and quarterly, thru DDR) -
         - CEO, CFO, individual with equivalent authority or direct delegate

PRACTICAL COMPLIANCE CONSIDERATIONS

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2. Provide truthful, accurate and complete information to customers
   - Examples - formulary dossier, discount and rebate communications with state P&Ts, VA/FSS, Medicaid Managed care, Part D plans
   - Adhere to policies and procedures addressing off-label discussions and outcomes/cost-effectiveness claims
3. Accurately characterize price concessions
   - If it is looks like a discount then call it, and account for it, as a discount
   - BMS (2007); Schering (2006); TAP (2001)
     - Alleged kickbacks resulted in BP violations
4. Refrain from billing and coding discussions with customers
5. Engage third party, independent parties to conduct FMV analysis on Bona Fide Service Fees
   - Privilege considerations

PRACTICAL COMPLIANCE CONSIDERATIONS

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6. Accurate paper
   - Good paper will not “fix” bad intent or practice
   - US ex rel. Westmoreland v. Amgen (2012): “Parties to a GPO arrangement cannot obtain safe harbor protection with a GPO contract that complies with the written agreement requirement of a safe harbor and appears, on paper, to meet all of the other safe harbor requirements, but that does not reflect the actual arrangement between the parties.”

KEY RESOURCES

- Cooley Health Beat Blog
  - www.cooleyhealthbeat.com
- Pharmaceutical/Medical Device Select Public Settlements Tracker
  - http://cooleyhealthbeat.com/resources/
- Links to Key Health Regulatory Resources
  - http://cooleyhealthbeat.com/resources/
  - 81 Fed. Reg. 5170 (Feb. 1, 2016) – Final AMP Rule
- Cooley's 20 Considerations in Implementing the Final AMP Rule in Your Organization

RESOURCES

- 81 Fed. Reg. 5170 (Feb. 1, 2016) – Final AMP Rule
- 20 Considerations in Implementing the Final AMP Rule in Your Organization, Cooley
- 68 Fed. Reg. 23731 (May 5, 2003) - OIG Compliance Program Guidance for Pharmaceutical Manufacturers