

**Statement
of the
American Hospital Association
before the
Health Subcommittee of the Committee on Energy & Commerce
of the
U.S. House of Representatives**

“Examining the Drug Supply Chain”

December 13, 2017

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, and our clinician partners – including more than 270,000 affiliated physicians, 2 million nurses and other caregivers – and the 43,000 health care leaders who belong to our professional membership groups, the American Hospital Association (AHA) appreciates the opportunity to submit for the record our comments on the drug supply chain and the cost of medications.

America’s hospitals rely on innovative drug therapies to save lives every day. Without them, more lives would be lost to diseases like cancer and AIDS, and others who now can live comfortably while managing their chronic conditions would see their quality of life deteriorate. In short, modern pharmaceuticals play a critical role in getting patients healthy and helping them maintain health. Hospitals primarily interact with the drug supply chain in their role as purchasers and dispensers of pharmaceuticals. They also play a crucial role in the development of new drug therapies.

Spending on pharmaceuticals has increased dramatically over the past several years. The burden of this increase falls on all purchasers, including patients and the providers who treat them. For example, hospitals frequently see patients show up in the emergency department or return for follow up care sicker than when they left because they were unable to afford their medications. Just as many patients face difficult choices when considering purchasing medications, hospitals, as drug purchasers, face significant resource constraints and trade-offs as spending on drugs increases.



The primary driver behind increased drug spending is higher prices, not increases in utilization. Within the health care field, “pharmaceuticals” was “the fastest growing category” in terms of pricing for every month of 2016 and for most months of 2017.¹ We see both higher launch prices for new drugs and increases in prices for existing drugs. Limited competition and drug shortages have facilitated this price growth.

Hospitals work with manufacturers and group purchasing organizations (GPOs) to negotiate the best prices for the drugs they use. However, for many drugs, the starting point for the negotiation is high, with some new drugs hitting the market at \$55,000,² \$475,000,³ and even \$750,000⁴ for a course of treatment. This price does not include the cost of managing and delivering the drug, or any of the ancillary services required to support the patient undergoing treatment.

We explore these challenges in more detail below.

HOW HOSPITALS AND HEALTH SYSTEMS INTERFACE WITH THE DRUG SUPPLY CHAIN

The drug supply chain is complicated, with a number of steps between the development and the delivery of a drug. America’s hospitals and health systems did not design the supply chain, but they do interface with it. At the very beginning of the chain, academic medical centers are responsible for a significant amount of the research used to develop and test new drugs. Closer to the end of the chain, all hospitals are major purchasers of drugs used in clinical settings. Below we provide more information on our members’ roles in the drug supply chain.

Research & Development. Academic medical centers play a leading role in both the development of the underlying science supporting new drug therapies (basic science research), as well as the development and testing of new therapies (applied or translational research). A combination of public and private funding supports this work, including grants from the National Institutes of Health, philanthropy and biopharmaceutical companies.

A report from Tufts University underlined that “a close and synergistic relationship between [the biopharmaceutical and academic medical center] sectors is critical to ensuring a robust national capacity.”⁵ The report noted that more than 50 percent of researchers at academic medical centers contribute to drug and device medical trials, and partnerships between biopharmaceutical companies and academic hospitals have increased in recent years.

A *New England Journal of Medicine* report underscored the benefits provided by public-sector research institutions (PSRI), which include academic medical centers and their affiliated universities. Specifically, the study’s authors found that PSRI were responsible for 153 drugs, vaccines or new indicators for existing drugs approved by the Food and Drug Administration (FDA) between 1970 and 2009. They also found that hospitals and PSRIs were predisposed to discover drugs that have a disproportionately important clinical effect⁶ and those that could be used for widespread public health concerns, including the treatment of cancer and infectious diseases, as well as vaccination development.⁷

Role as Purchasers and Providers. Hospitals purchase drugs that clinicians use to treat patients in their facilities. Hospitals use several different approaches to acquire drugs. Nearly all hospitals work with GPOs to negotiate prices with manufacturers and to contract with wholesalers for delivery. GPOs enable hospitals to reduce administrative expenses by precluding the need to maintain the staff it would take to negotiate contracts for thousands of drugs. Instead, by relying on GPOs, this contracting function, which is not insignificant, is shared across hundreds or thousands of hospitals. This also often enables hospitals to achieve the best price, as they benefit from the negotiating power the GPO has as a result of aggregating purchasing volume. GPOs can save hospitals 10 to 18 percent on the cost of drugs.⁸ Hospitals pay GPOs in different ways, which may include a combination of upfront administrative fees, transaction fees and/or a percentage of discount obtained. One report found that GPOs save the health care system between \$25 billion and \$55 billion per year.⁹

Most hospitals do retain some direct contracting with drug manufacturers. This is primarily true for branded therapies for which there is no competition. In these instances, manufacturers are not compelled to negotiate with GPOs. In those instances, hospitals may directly negotiate with the manufacturer and contract with the wholesaler for delivery. Only a handful of hospitals directly contract for all of their drug supply. These are larger organizations that have both the patient volume and the staff capacity to make one-on-one negotiations worthwhile. A significant challenge arises for small hospitals that have neither the staff capacity nor the volume to enter into direct negotiations with manufacturers. In some instances, small, rural hospitals have been unable to obtain access to certain therapies.

Whether hospitals are contracting directly or relying on GPOs, the pharmaceutical manufacturers set the starting price in negotiations. The ability of the GPO or hospital to obtain a discount off this initial price largely has to do with volume and whether, and how much, competition for such a therapy exists. In instances where no competition exists, such as for many of the new, high-cost specialty drugs, large discounts are not available.

Once a hospital acquires a drug, it manages the supply in hospital-based pharmacies. Hospital pharmacists work with prescribing clinicians to develop and manage the formulary and follow standards for formulary development, which takes into account “evidence-based clinical, ethical, legal, social, philosophical, quality-of-life, safety and economic factors that result in optimal patient care.”¹⁰ Pharmacists also manage the dispensing of medications to the appropriate clinical staff, who then deliver the drug to the patient.

HOSPITAL EXPERIENCE WITH DRUG SPENDING

Purchasers of prescription drugs have faced significant increases in spending over the past several years. Last week, the Centers for Medicare & Medicaid Services (CMS) released updated National Health Expenditures (NHE) data that showed that retail drug spending increased by 1.3 percent in 2016. While this level of growth may appear low, it follows two consecutive years of expansive growth in retail drug spending: 12.4 percent in 2014 and 8.9 percent in 2015. In other words, the lower growth comes on top of a much higher spending base for drugs. In addition, these figures capture *retail* drug spending only; they do *not* include spending on drugs purchased by providers, such as hospitals.

Detailed non-retail drug spending data is not publicly available, as it is not easily collected. Nearly all payments to hospitals for inpatient care are made on a per discharge (Diagnostic Related Group or DRG) or per diem basis, which means that all input costs are rolled into a single payment. Hospitals are responsible for managing input costs within that fixed payment amount and not all input costs are systematically reported publicly.

In order to explore the experience of non-retail drug purchasers, the AHA and the Federation of American Hospitals worked with the NORC at the University of Chicago last year to collect and evaluate data on inpatient drug spending (see Appendix A). The NORC found that increases in drug spending for inpatient care outpaced what the NHE reported for retail drug spending. ***Specifically, the NORC found that while retail spending on prescription drugs increased by 10.6 percent between 2013 and 2015, hospital spending on drugs in the inpatient space rose 38.7 percent per admission during the same period.***^{11 12}

Price, not volume, is the primary driver of this increased spending. After examining data from two GPOs that collectively purchase drugs for more than 1,400 hospitals, the NORC was able to track changes in price, utilization and total spending for a select group of drugs. Consistently, changes in pricing drove increases in spending. These price increases, from the hospitals' perspective, appeared to be random, inconsistent and unpredictable: large unit price increases occurred for both low- and high-volume drugs and for both branded and generic drugs.

Our members were not surprised to learn that their purchasing experience differs from what the NHE reports for retail drugs. In testimony to the Committee on Oversight and Government Reform of the U.S. House of Representatives, one drug manufacturer acknowledged targeting hospital-administered drugs for price increases. Howard Schiller, then-interim CEO and director of Valeant Pharmaceuticals, stated: "Because these drugs are hospital-administered, and not purchased by patients directly, increasing the cost of the drugs to hospitals would affect the hospital's profits on these procedures, but it should not reduce patient access."¹³

While the NORC study supports Mr. Schiller's admission that manufacturers target hospitals for price increases, we challenge his assessment that such practices do not reduce patient access. Researchers at the Cleveland Clinic found that patient access to Valeant drugs nitroprusside and isoproterenol declined after the company increased the prices for both substantially. From 2012 to 2015, 53 percent fewer patients were treated with nitroprusside and 35 percent less were treated with isoproterenol.¹⁴ This is because hospitals bear a heavy burden when the cost of drugs increases, in large part due to how hospital reimbursement is structured, and this has direct implications for the availability of certain drug therapies. Medicare, which is one of the largest payers for most hospitals and on which many commercial insurers base their rates, cannot keep up with new and frequently changing drug prices. The program relies on drug pricing data collected and reported by the Bureau of Labor Statistics, which does a full "refresh" of drug pricing information only every five to seven years. This data lag means that hospital reimbursement does not necessarily increase proportionally to drug price increases. As a result, hospitals must divert other resources to cover higher drug costs, forcing difficult choices between providing adequate compensation to employees, many of whom are highly skilled in professions

facing shortages; upgrading and modernizing facilities; purchasing new technologies to improve care; or paying for drugs.

A number of factors contribute to the increase in drug spending, and those factors have evolved over time. In the past several years, hospitals have faced widespread price increases on existing drugs. While drug manufacturers have increased some prices by multiple hundreds or even thousands of percent, hospitals report that the 10 to 20 percent increases on widely used generic drugs often have a greater impact on their budgets given the high volumes of these drugs that hospitals purchase. Increasingly, our members report that high *launch* prices and increased spending due to drug shortages are new challenges they face, as well as budget pressures associated with the ancillary service costs associated with highly complex and potent drugs.

High Launch Prices. Drug manufacturers are increasing the launch prices for new drugs. These prices are the basis for negotiations with purchasers. Examples of recent launch prices include:

- Talz (Eli Lilly), used for treating psoriasis, costs \$50,000 a year.¹⁵
- Keytruda (Merck), used for treating melanoma, costs \$152,400 a year.¹⁶
- Kymriah (Novartis), used for treating leukemia, costs \$475,000 for a course of treatment.¹⁷
- Spinraza (Biogen), used to treat spinal muscular atrophy, costs \$750,000 for the first year of treatment and \$375,000 per year thereafter.¹⁸

Drug Shortages. Drug shortages also are a major contributor to increases in drug spending. Medications that experience shortages are largely injectable products that are off patent and have few suppliers; shortages typically arise from quality concerns that cause a halt to production. If a product has few competitors, this disruption cannot be absorbed by other companies and demand outpaces supply. This not only results in a shortage, but also causes prices to rise. For drugs with a sole manufacturer, shortages are exacerbated – since there is no alternative, clinicians must scramble to find the drug or compound the drug in cases where it is possible. They also may recommend an alternative (often less effective) therapy, if one exists. This, in turn, can result in higher spending because manufacturers often capitalize on the situation by increasing the price of the alternative therapy. For example, a 2017 study that examined how drug prices change during supply disruptions¹⁹ found that after quality-control issues forced a manufacturer of glycopyrrolate – an injectable agent commonly used before surgery to reduce secretions – to suspend production, the remaining manufacturer increased the price of its product by 855 percent. The list price remained at the new level even after production capacity was restored.

Ancillary Costs. Many new drug therapies are highly potent and come with significant side effects. A recent example is Kymriah, a new blood cancer drug using “CAR-T cell therapy” through which patients’ own genes are extracted, modified and reinserted to kill leukemia cells. The potential side effects require extensive ancillary services to monitor patients and prevent infections and other adverse events for a prolonged period of time.

According to the FDA, “Treatment with Kymriah has the potential to cause severe side effects. It carries a boxed warning for cytokine release syndrome (CRS), which is a systemic response to the activation and proliferation of CAR T-cells causing high fever and flu-like symptoms, and

for neurological events. Both CRS and neurological events can be life-threatening. Other severe side effects of Kymriah include serious infections, low blood pressure (hypotension), acute kidney injury, fever, and decreased oxygen (hypoxia). Most symptoms appear within one to 22 days following infusion of Kymriah. Since the CD19 antigen is also present on normal B-cells, and Kymriah will also destroy those normal B cells that produce antibodies, there may be an increased risk of infections for a prolonged period of time²⁰ (emphasis added).

While these services do not directly increase the cost of the drug, they do impact the overall cost of care.

HOSPITALS' APPROACH TO REDUCING DRUG COSTS

Hospitals and health systems are committed to ensuring patients receive high-value care. Hospital pharmacists continually work to reduce the costs of drug therapies in order to maintain and expand access to care. Specific examples of approaches taken by hospitals include:

- Identifying equally effective and safe alternative therapies that may be less costly;
- Ongoing monitoring of pricing changes to anticipate upcoming needs;
- Improving inventory management, including by changing how and where medicines are stocked and how they are delivered to clinicians;
- Reducing waste by identifying safe approaches to splitting excessively large single dose vials into multiple doses; and
- Compounding therapies in-house.

Despite these efforts, increased drug spending remains a challenge and one which we believe requires legislative and regulatory intervention. We urge Congress and the Administration to support patients and providers by taking immediate action to reign in the rising cost of drugs, including by passing the Creating and Restoring Equal Access to Equivalent Samples Act (CREATES Act) and protecting the 340B Program. We also offer a broader set of comprehensive solutions in Appendix B.

The CREATES Act. Generic drugs are one tool for reducing drug prices, as they increase competition after the monopoly enjoyed by drug manufacturer ends when a drug's patent expires. The CREATES Act targets two forms of anticompetitive behavior that are being used to block and delay entry of generic drugs. The first is known as sample-sharing. This occurs when brand-name drug companies refuse to sell samples of their product to potential generic competitors so the generic company cannot perform testing to show that its product is bioequivalent to the brand-name product, a prerequisite for approval by the FDA. The second involves participation in a shared safety protocol. This occurs when brand-name manufacturers whose products require a distribution safety protocol refuse to allow generic competitors to participate in that safety protocol, which is needed to gain FDA approval. The CREATES Act allows a generic drug manufacturer facing the sample-sharing delay tactic to bring an action in federal court for injunctive relief, such as to obtain the sample it needs. The bill also authorizes a judge to award damages to deter future delaying conduct. **We urge Congress to pass the CREATES Act.**

The 340B Program. Congress created the 340B program to permit safety-net hospitals that care for communities with a high number of low-income and uninsured patients “to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.”²¹ Section 340B of the Public Health Service Act requires pharmaceutical manufacturers participating in Medicaid to sell outpatient drugs at discounted prices to these health care organizations. For 25 years, the 340B program has been critical in helping hospitals expand access to lifesaving prescription drugs and comprehensive health care services to communities across the country with a high number of low-income and uninsured individuals, *at no cost to the federal government*.

Given the increasingly high cost of pharmaceuticals, the 340B program provides critical support to help hospitals’ efforts to build healthy communities. In 2015, the 340B program accounted for only 2.8 percent of the \$457 billion in annual drug purchases made in the U.S. However, hospitals were able to use those savings to support many programs that are improving and saving lives.²²

Thirty percent of the hospitals that serve 340B communities are located in rural communities. Nearly 50 percent of those hospitals’ communities significantly exceeded the minimum Medicare disproportionate share hospital (DSH) adjustment percentage of 11.75 percent, which is the qualifying threshold for the 340B program. In fact, one-fifth of these hospitals have a Medicare DSH adjustment percentage of more than 25 percent. Many 340B hospitals are financially vulnerable, and in 2015, one out of every four hospitals had a negative operating margin.²³

The 340B program enables these hospitals to serve their communities by reinvesting savings from reduced drug pricing into programs that benefit their patients, particularly their vulnerable patients. In 2015, 340B hospitals provided \$23.8 billion in uncompensated care.²⁴ Examples of programs provided by 340B hospitals include:

- Financial assistance programs for patients unable to afford their prescriptions;
- Provision of clinical pharmacy services, such as disease management programs or medication therapy management;
- Increased access to other medical services, such as obstetrics, diabetes education, oncology services and other ambulatory services;
- Establishment of additional outpatient clinics to improve access to care;
- Community outreach programs; and
- Free vaccinations for vulnerable populations.

In addition, an examination of hospital services illustrates that 340B hospitals provide access to essential services to their communities:²⁵

- Nearly two-thirds of 340B hospitals provide **trauma care**.
- Three-quarters of 340B hospitals provide **pediatric medical surgical services**.
- Nearly all 340B hospitals have **obstetrics (OB) units**.
- Approximately two-thirds of 340B hospitals provide **psychiatric services**.
- 42 percent of 340B hospitals provide **substance abuse or dependency services**.

- 58 percent of 340B hospitals have **Neonatal Intensive Care Units (NICUs)**.
- Nearly all 340B hospitals provide **breast cancer screening**.

The 340B program is under threat, especially as a result of a recent change in Medicare payment policy that reduces by nearly 30 percent, or \$1.6 billion, Medicare payments to certain hospitals for outpatient drugs purchased under the 340B program. Cuts of this magnitude will negate the intent of the program, reducing resources that hospitals use to expand access to care and services to vulnerable communities. **We urge Congress to pass H.R. 4392, which would prevent these cuts from going into effect and reducing critical health care resources in vulnerable communities.**

CONCLUSION

We appreciate the opportunity to provide these comments and support the Committee's efforts and attention to examining the issue of the drug supply chain and the cost of medications. We remain deeply committed to working with Congress, the Administration and other health care stakeholders to ensure that all Americans can access the drug therapies they need to lead healthy, happy and productive lives.

¹ Altarum Institute, "Price Briefs," [October 2017](#), [September 2017](#), [August 2017](#), [July 2017](#), [June 2017](#).

² Toich, L., "Will Hepatitis C Virus Medication Costs Drop in the Years Ahead?" Pharmacy Times, February 8, 2017. <http://www.pharmacytimes.com/resource-centers/hepatitisc/will-hepatitis-c-virus-medication-costs-drop-in-the-years-ahead>

³ Sagonowsky, E. "At \$475,000, is Novartis' Kymriah a bargain—or another example of skyrocketing prices?" FiercePharma, August 31, 2017, <https://www.fiercepharma.com/pharma/at-475-000-per-treatment-novartis-kymriah-a-bargain-or-just-another-example-skyrocketing>

⁴ Picci, A., "The cost of Biogen's new drug: \$750,000 per patient," CBS News, December 16, 2016. <https://www.cbsnews.com/news/the-cost-of-biogens-new-drug-spinraza-750000-per-patient/>

⁵ Milne, Christopher-Paul, et al. Academic-Industry Partnerships for Biopharmaceutical Research & Development: Advancing Medical Science in the U.S. Tufts Center for the Study of Drug Development. April 2012. http://csdd.tufts.edu/files/uploads/tuftscsdd_academic-industry.pdf

⁶ Forty-six percent of drugs developed by PSRIs received priority reviews from the FDA – an indication that the drugs offered a substantial improvement over existing treatments. Only 20 percent of new drugs from the private sector received a priority review designation.

⁷ Stevens, Ashley J., et al. The Role of Public-Sector Research in the Discovery of Drugs and Vaccines. New England Journal of Medicine 364: 535-541. February 2011.

⁸ DeBenedette, V., "The Evolution of Group Purchasing Organizations," Modern Medicine, October 10, 2016. <http://drugtopics.modernmedicine.com/drug-topics/news/evolution-group-purchasing-organizations?page=0,3>

⁹ Ibid.

¹⁰ American Society for Health-System Pharmacists, "ASHP Guidelines on the Pharmacy and Therapeutics Committee and the Formulary System," Accessed Dec. 9, 2017 at: <https://www.ashp.org/-/media/assets/policy-guidelines/docs/guidelines/gdl-pharmacy-therapeutics-committee-formulary-system.ashx?la=en&hash=EF1E4214CC91C65097AEEEECE91BF6EC985AE3E56>

¹¹ National Health Expenditure Data for 2013 - 2015

¹² "Trends in Hospital Inpatient Drug Costs: Issues and Challenges," American Hospital Association and the Federation of American Hospitals, October 11, 2016. <http://www.aha.org/content/16/aha-fah-rx-report.pdf>

¹³ Statement of Howard B. Schiller, Interim Chief Executive Officer and Director, Valeant Pharmaceuticals International, Inc. before the Committee on Oversight and Government Reform of the U.S. House of Representatives, February 4, 2016. <https://oversight.house.gov/wp-content/uploads/2016/02/Statement-of-Howard-Schiller-2016-02-04.pdf>

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- ¹⁴ Khot UN, et al. Nitroprusside and Isoproterenol Use after Major Price Increases, *New England Journal of Medicine*, August 10, 2017. <http://dx.doi.org/10.1056/NEJMc1700244>
- ¹⁵ Waxman, H. et.al, “Getting to the Root of High Prescription Drug Prices: Drivers and potential solutions,” Commonwealth Fund, Jul 2017. http://www.commonwealthfund.org/~media/files/publications/fund-report/2017/jul/waxman_high_drug_prices_drivers_solutions_report.pdf?la=en
- ¹⁶ Szabo, L., “As Drug Costs Soar, People Delay Or Skip Cancer Treatments,” National Public Radio, Mar. 15, 2017, <https://www.npr.org/sections/health-shots/2017/03/15/520110742/as-drug-costs-soar-people-delay-or-skip-cancer-treatments>
- ¹⁷ Sagonowsky, E. “At \$475,000, is Novartis' Kymriah a bargain—or another example of skyrocketing prices?” FiercePharma, August 31, 2017, <https://www.fiercepharma.com/pharma/at-475-000-per-treatment-novartis-kymriah-a-bargain-or-just-another-example-skyrocketing>
- ¹⁸ Picci, A., “The cost of Biogen’s new drug: \$750,000 per patient,” CBS News, December 16, 2016. <https://www.cbsnews.com/news/the-cost-of-biogens-new-drug-spinraza-750000-per-patient/>
- ¹⁹ Davies, B., Hwang, T., and Kesselheim, A., “Ensuring Access to Injectable Generic Drugs — The Case of Intravesical BCG for Bladder Cancer,” *New England Journal of Medicine*, April 13, 2017.
- ²⁰ Food & Drug Administration, “FDA approval brings first gene therapy to the United States,” August 30, 2017. <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm574058.htm>
- ²¹ <https://www.hrsa.gov/opa/index.html>
- ²² Assistant Secretary for Planning and Evaluation, “Issue Brief: Observations on Trends in Prescription Drug Spending,” March, 2016. <https://aspe.hhs.gov/system/files/pdf/187586/Drugspending.pdf> and The Health Resources and Services Administration, “FY 2018 Justification of Estimates for Appropriations Committees,” <https://www.hrsa.gov/sites/default/files/hrsa/about/budget/budget-justification-2018.pdf>
- ²³ AHA 2015 Annual Survey Data
- ²⁴ AHA 2015 Annual Survey Data
- ²⁵ Ibid.

FINAL REPORT

Trends in Hospital Inpatient Drug Costs: Issues and Challenges

OCTOBER 11, 2016

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Preface

October 11, 2016

The price of prescription drugs has skyrocketed over the past several years. It seems that every day we hear a new report of how the cost of drugs hurts patients. When the price of a two-pack of Epipens jumped from \$100 to \$600 between 2007 and 2016 – an increase of 500 percent – parents around the country wondered if they would be able to acquire this life-saving medication for their children. When the cost of the infection-control drug Daraprim went from \$13.50 to \$750 a pill overnight, real patients ended up in the hospital when they could not follow their treatment regimens.

These price increases are extremely troublesome throughout the health care system. They not only threaten patient access to drug therapies, but also challenge providers' abilities to provide the highest quality of care. Drug costs also are a major factor in the rising cost of health care coverage.

Hospitals bear a heavy financial burden when the cost of drugs increases and must make tough choices about how to allocate scarce resources. One hospital put the challenge starkly: last year, the price increases for just four common drugs, which ranged between 479 and 1,261 percent, cost the same amount as the salaries of 55 full-time nurses. And while nearly everyone can agree that price increases in the hundreds or thousands of percent are unjustifiable, many hospitals report that annual price increases of 10 or 20 percent on widely-used older generic drugs can have an even greater effect, given the large quantities that a hospital must purchase. Managing these skyrocketing cost increases forces difficult choices between providing adequate compensation to employees, many of whom are highly skilled in professions facing shortages; upgrading and modernizing facilities; purchasing new technologies to improve care; or paying for drugs, especially when these price increases are not linked to new therapies or improved outcomes for patients.

The American Hospital Association and the Federation of American Hospitals commissioned this study to better understand how drug prices are changing in the inpatient hospital setting. Given that inpatient hospital services are generally reimbursed under a bundled payment model, there is no single source for information on how much hospitals spend on drugs and how that amount has changed over time. We intend for this study to help inform policymakers and other stakeholders about the challenges hospitals face in acquiring life-saving treatments, and serve as a basis for further evaluating how drug prices impact the patients we serve.



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TABLE OF CONTENTS

- EXECUTIVE SUMMARY1**
 - Background.....2
 - Study Objectives.....4
 - Definitions.....4

- METHODS.....5**
 - Study Population and Data Sources.....5
 - Analysis6

- KEY FINDINGS10**

- CONCLUSIONS17**
 - Limitations.....18

- APPENDIX19**

List of Tables

Table 1.	Target Population and Study Sample	6
Table 2.	Key Characteristics of Sampled Hospitals Compared to all U.S. Community Hospitals	7
Table 3.	Key Characteristics of Sampled GPO Hospitals Compared to all U.S. Community Hospitals	9

List of Figures

Figure 1.	Inpatient Drug Spending per Admission Has Increased Substantially Since 2013	10
Figure 2.	Over 90% of Hospital Administrators Reported That Higher Drug Prices Had a Moderate or Severe Impact on Their Budgets.....	11
Figure 3.	Growth in Inpatient Drug Spending Has Far Outpaced Payer Reimbursement and Pharmaceutical Price Inflation	12
Figure 4.	Inpatient Drug Spending Growth Eclipsed Retail Prescription Drug Spending Growth	13
Figure 5.	Drugs with the Highest Spending Experienced Significant Price Increases in 2014 and 2015	15
Figure 6.	Drugs with the Highest Price Increases between 2013 and 2015 Also Experienced Significant Spending Increases.....	16
Table A1.	Change in Unit Cost for Top Ten Drugs with Highest Total Spending in CY2015 (GPO Data).....	19
Table A2.	Top Ten Drugs with Highest Unit Price Increases in CY2015 (GPO Data)	19
Table A3.	Glossary.....	20

EXECUTIVE SUMMARY

While there has been recent high profile media coverage of retail drug price increases, the hospital inpatient pharmaceutical market is often overlooked and is not systematically evaluated. This report presents recent trends in hospital inpatient drug prices and spending, providing policymakers and others with quantifiable information on challenges posed by recent increases in inpatient drug prices.

In conjunction with the American Hospital Association and the Federation of American Hospitals, NORC conducted a survey of all U.S. community hospitals and analyzed survey results of 712 responding to the survey. Additionally, two group purchasing organizations (GPOs) representing over 1,400 community hospitals contributed price and spending data on a subset of drugs. The drugs sampled were identified by expert hospital pharmacy workgroups as being high-spend due to volume, price, or both, or as having experienced substantial price increases in recent years.

Between FY2013 and FY2015, inpatient drug spending increased an average 23.4 percent annually, and on a per admission basis, by 38.7 percent. Over 90 percent of responding hospitals reported that recent inpatient drug price increases had a moderate or severe effect on their ability to manage the overall cost of patient care, with one-third of the respondents indicating that the impact was severe. Many of the sampled drugs that experienced substantial unit price increases in CY2014 and CY2015 were high volume drugs. In most cases, the sampled drugs were not new entrants. This report provides a valuable look at a section of the pharmaceutical market that affects hospitals and the patients they serve.

Key Findings

- Average annual inpatient drug spending increased by 23.4 percent between FY2013 and FY2015.
- Inpatient drug spending increased on a per admission basis by 38.7 percent during the same period.
- Growth in unit price – not volume - was primarily responsible for the increase in total inpatient drug spending.
- Over 90 percent of surveyed hospitals reported that inpatient drug price increases had a moderate or severe effect on their ability to manage costs.
- Due to delays in refreshing the pharmaceutical index, Medicare reimbursement cannot keep pace with rapidly increasing drug prices.
- The growth in spending on inpatient drugs exceeds the growth in spending on retail drugs.
- Price increases appear to be random, inconsistent, and unpredictable: large unit price increases occurred for both low- and high-volume drugs and for both branded and generic drugs. About half of the drugs sampled had no generic competition.

Background

Total net spending on prescription drugs, inclusive of discounts, has accelerated over the past year to \$309.5 billion annually, making prescription drugs the fastest growing segment of the U.S. healthcare economy.^{1,2} Growth in spending on drugs in 2014 (12.2 percent) dwarfs the overall rate of health care spending growth (5.3 percent) as well as the rate of spending growth on hospital and physician care (4.1 and 4.6 percent, respectively).³ The price of drugs – not utilization – is the predominant contributor to increased drug spending. While spending on drugs rose 8.5 percent in 2015, total prescriptions dispensed increased by only 1 percent.⁴ The Bureau of Labor Statistics (BLS) Producer Price Index (PPI) suggests that pharmaceutical price inflation was 7.2 percent in 2015, greatly outpacing both general inflation (0.7 percent) and medical inflation (2.7 percent).⁵

Healthcare purchasers, including federal and state governments, insurers, individual consumers, and providers, have identified the rising cost of drugs as a major challenge for retaining patient access to care. Hospitals bear a heavy financial burden when the cost of drugs increases. Hospitals are significant purchasers of prescription drugs, such as anesthesia and antibiotics to prevent infections during surgery. They also treat patients suffering the repercussions of being unable to afford or otherwise access their medications, often when these individuals return through the emergency department.

While existing studies have quantified the rate of increase in retail drug prices and spending, data limitations have prevented a more detailed examination of the impact of high and rising drug prices on hospitals and their patients.^{6,7} This study sought to document the extent to which inpatient drug prices and spending have increased in the inpatient setting, allowing policymakers and others to examine the impact such changes may have on patients.

¹ IMS Health, “Medicines Use and Spending in the U.S. – A Review of 2015 and Outlook to 2020,” <http://www.imshealth.com/en/thought-leadership/ims-institute/reports/medicines-use-and-spending-in-the-us-a-review-of-2015-and-outlook-to-2020#form>.

² Total spending on an invoice price basis in FY2015 was \$425 billion.

³ Centers for Medicare & Medicaid Services. “National health expenditure fact sheet.” Baltimore, MD: US Department of Health & Human Services (2015).

⁴ IMS Health, “IMS Health Study: U.S. Drug Spending Growth Reaches 8.5 Percent in 2015,” April 14th, 2016, <http://www.imshealth.com/en/about-us/news/ims-health-study-us-drug-spending-growth-reaches-8.5-percent-in-2015>.

⁵ U.S. Department of Labor, U.S. Bureau of Labor Statistics. PPI Detailed Report: December 2015, <http://www.bls.gov/ppi/ppidr201512.pdf>

⁶ Leigh Purvis and Stephen Schondelmeyer, “Rx Price Watch Report: Trends in Retail Prices of Prescription Drugs Widely Used by Older Americans: 2006 to 2013,” AARP Public Policy Institute, http://www.aarp.org/health/drugs-supplements/info-08-2010/rx_price_watch.html.

⁷ Allan Coukell and Chuck Shih, “What’s Driving Increased Pharmaceutical Spending?,” The Pew Charitable Trust, 2016. <http://www.pewtrusts.org/en/research-and-analysis/analysis/2016/05/26/whats-driving-increased-pharmaceutical-spending>.

As large purchasers, hospitals appear to be particular targets for drug price increases. At least one pharmaceutical company, Valeant, specifically looked to increase prices for hospital-administered drugs.⁸ These increases can be dramatic. In 2015, Valeant raised the list prices of Isuprel and Nitropress, common heart medications, by an average of more than 200 percent and 500 percent respectively.⁹ These increases may be higher at individual hospitals: for example, the Cleveland Clinic reported price increases for these two drugs of 310 and 718 percent, respectively, and the hospital spent more than \$5.3 million on them alone that year. These are just some examples of the price increases reflected in national data.¹⁰

From the beginning, a key selling point advanced by Marathon was data that it had accumulated showing that Nitropress and Isuprel were mispriced relative to their value to hospitals... we elected to implement significant price increases immediately upon purchasing the drugs. In retrospect, we relied too heavily on the industry practice of increasing the price of brand name drugs in the months before generic entry.
 -- J. Michael Pearson, Chief Executive of Valeant Pharmaceuticals

The way in which hospitals are reimbursed compounds the impact of increasing drug costs. Most hospitals are not directly reimbursed for the drugs they purchase for use in the inpatient setting.¹¹ Instead, they generally receive a single payment for all non-physician services, including drugs, that they provide during an inpatient stay or, less commonly, each inpatient day (per diem). For example, Medicare, which accounts for a significant source of payments to hospitals for inpatient services nationally, uses a reimbursement system that cannot keep pace with changes in drug prices. Some commercial and

other payers either use the Medicare payment model, called the Inpatient Prospective Payment System (IPPS),¹² or pay directly based on the Medicare rate, e.g., as a percentage of Medicare reimbursement. When reimbursement rates cannot keep up with input costs, such as drugs, hospitals must absorb the excess.

Each year, CMS evaluates changes in the prices of goods and services required to furnish acute inpatient care for purposes of updating the IPPS. For purposes of evaluating changes in drug prices, CMS uses the

⁸ Committee on Oversight and Government Reform, “Memorandum Re: Documents Obtained by Committee from Valeant Pharmaceuticals,” 2016, <http://democrats.oversight.house.gov/sites/democrats.oversight.house.gov/files/documents/Memo%20on%20Valeant%20Documents0.pdf>.

⁹ Brady Dennis, “Rattled by Drug Price Increases, Hospitals Seek Ways to Stay on Guard,” *The Washington Post*, March 13th, 2016, https://www.washingtonpost.com/national/health-science/rattled-by-drug-price-increases-hospitals-seek-ways-to-stay-on-guard/2016/03/13/1c593dea-c8f3-11e5-88ff-e2d1b4289c2f_story.html.

¹⁰ Katie Thomas, “Valeant Promised Price Breaks on Drugs. Heart Hospitals are Still Waiting,” *The New York Times*, May 11th, 2016, <http://www.nytimes.com/2016/05/12/business/valeant-promised-price-breaks-on-drugs-heart-hospitals-are-still-waiting.html>.

¹¹ Some small, rural hospitals, called Critical Access Hospitals, are reimbursed on a cost basis.

¹² Under the IPPS, hospitals are paid a single pre-determined amount that is based on a national base payment rate, which is adjusted to account for factors such as a patient’s condition, the treatment provided, and local market conditions that affect hospitals’ costs of providing care. The national base payment rate reflects the capital and operating costs that “efficient” hospitals are expected to incur for providing inpatient services. The capital and operating base payments are updated annually to account for changes in patient case mix, market conditions, and other factors.

BLS PPI prescription drug component, which in turn relies on manufacturers to provide timely information on prices. The BLS reviews a sample of drugs that it selects based on probability proportionate to size (dollar value). The BLS refreshes the pharmaceuticals index every five to seven years to allow entirely new products or new trends in the market to be incorporated into the sample.¹³ To address the continuous introduction of new drugs, the BLS draws supplemental samples every year.¹⁴ However, these annual samples do not include existing drugs that may have experienced significant price increases in a very short period of time. Thus, the delay in refreshing the pharmaceuticals index fails to capture sudden price increases. Rapid and unpredictable changes in drug prices adversely affect hospitals due to their reimbursement model.

Study Objectives

This study aims to evaluate trends in hospital inpatient drug prices and spending nationwide and assess the impact of such trends on hospitals. Because most payers reimburse hospitals for inpatient services using a predetermined, fixed payment model, data does not readily exist on the price of drugs or other services that are used in the inpatient setting. This study used a large sample survey design to obtain data on this largely unknown market. The study targeted the following research questions:

- Did inpatient drug spending increase between FY2013 and FY2015?
- To what extent was price – not volume – a contributor to changes in inpatient drug spending?
- To what extent have changing drug costs impacted hospitals' ability to manage costs within a predetermined, fixed-amount payment system?

Definitions

This study used the following definitions:

Inpatient drug spending per admission. This study includes hospital-based pharmacy spending on prescription drugs (injectable, non-injectable, and biological products) in inpatient settings during the fiscal year net of discounts. Radiopharmaceuticals are excluded from the estimates. Inpatient drug spending is divided by total admissions per year¹⁵ to calculate inpatient drug spending per admission for each sampled hospital.

¹³ Bureau of Labor Statistics (US). The Pharmaceutical Industry: an Overview of CPI, PPI, and IPP Methodology. 2011.

¹⁴ The FDA Orange books list all new drugs approved for marketing in the United States.

¹⁵ Number of hospital admissions are derived from the AHA annual survey.

Community hospitals: All nonfederal, short-term general, and other specialty hospitals. Other specialty hospitals include obstetrics and gynecology; eye, ear, nose, and throat; rehabilitation; orthopedic; and other individually described specialty services. Community hospitals include academic medical centers or other teaching hospitals if they are nonfederal short-term hospitals. Excluded are hospitals not accessible by the general public, such as prison hospitals or college infirmaries.

Price: Price in this report is typically referred to as unit cost or unit purchase cost. For average price, weighted averages were taken based on spending on a drug across different suppliers, formulations and dosages. Prices are inclusive of all discounts, including those offered as volume-based discounts as well as those rebates offered for drugs of varying market competitiveness and relative efficacy.

Total spending: The total amount spent on a drug across inpatient community hospitals responding to the survey.

METHODS

Study Population and Data Sources

The study population includes all U.S. community hospitals. According to the 2014 AHA Annual Survey, there are 4,369 community hospitals in the United States.

This study utilized several complementary data sources. First, we share data collected through a survey sponsored by the American Hospital Association (AHA) and the Federation of American Hospitals (FAH) that targeted all U.S. community hospitals (the Drug Survey). Second, we analyze aggregate prescription drug purchasing information from two group purchasing organizations (GPOs). Third, the study uses information on hospitals' characteristics from the 2014 AHA Annual Survey. Finally, NORC, the AHA and the FAH interviewed key stakeholders from a variety of inpatient settings to supplement the study with qualitative findings on changes in inpatient drug prices.

The Drug Survey was administered using the AHA's Annual Survey web-based platform, and was fielded for two months between April and June 2016. Of the sampled hospitals, 778 hospitals responded. Of the 778 responding hospitals, data from 712 hospitals remained in the survey after data cleaning and quality assurance processes (Table 1).

The GPO data include aggregate inpatient prescription drug purchase cost information for 28 selected drugs for more than 1,400 U.S. community hospitals. Approximately, 38% percent of these hospitals also responded to the Drug Survey. The sampled drugs were selected by expert pharmacist and hospital budget

workgroups because they are either drugs with high inpatient spend or drugs that have experienced substantial price increases in the past several years. Total spending for these drugs for all hospitals in the two GPO networks amounted to \$972,208,384 in CY2015.

Table 1. Target Population and Study Sample

Population and Sample Definition	Number of Hospitals
All U.S. Community Hospitals*	4,369
U.S. Community Hospitals Responding to AHA-FAH Drug Survey^	712
All Community Hospitals Belonging to Two Sampled GPO Networks*~	More than 1,400

* Source: 2014 AHA Annual Survey

^ Source: AHA-FAH Drug Survey

~Source: 2014 AHA Annual Survey; GPO Rx Data

Analysis

The study used survey weights to account for overall selection probability of each responding community hospital in the Drug Survey and make the results nationally representative. We used Taylor series variance estimation to compute standard errors. We applied post-stratification weight adjustments to calibrate the survey weights so that they sum to known population totals for key hospital characteristics. We obtained the population totals from the recent census of U.S. community hospitals in the 2014 AHA Annual Survey data set. Post-stratification weight adjustments resulted in reduced variance and bias in the final survey estimates. As shown in Table 2, compared to all U.S. community hospitals, a larger proportion of hospitals responding to the survey were for-profit; belonged to a hospital system; participated in a GPO network; were located in an urban setting; lacked a critical access hospital designation; were designated as teaching hospitals; and were larger in size in terms of number of beds and total Medicare discharges. After post-stratification adjustments were made to the survey weights, survey respondents matched the census of U.S. community hospitals from the 2014 AHA Annual Survey, across all key characteristics.

To estimate inpatient drug spending per hospital admission, information on number of admissions for each surveyed hospital was sourced from the 2013 and 2014 AHA Annual Surveys. Information on number of admissions for FY2015 was not available at the time this report was published. Since volume of admissions was similar between 2013 and 2014, we assumed that volume of admissions in 2015 was similar to 2014.¹⁶

¹⁶ 2013 AHA Annual Survey, 2014 AHA Annual Survey.

Table 2. Key Characteristics of Sampled Hospitals Compared to all U.S. Community Hospitals

Hospital Characteristic	All U.S. Community Hospitals	Sampled Community Hospitals	
		Unweighted	Weighted [95% CI]
Number of Hospitals	4,369	712	4,369
Ownership			
Government	22.5%	13.9%	22.5% [18.5% - 27.2%]
Not-for-profit	61.8%	57.3%	61.8% [57.3% - 66.1%]
For-profit	15.6%	28.8%	15.6% [13.3% - 18.2%]
Hospital System			
Yes	60.9%	75.4%	60.9% [56.2% - 5.4%]
No	39.1%	24.6%	39.1% [34.6% - 43.8%]
Group Purchasing Organization			
Yes	74.7%	76.3%	74.7% [70.5% - 78.5%]
No	1.8%	1.4%	1.8% [0.8% - 3.8%]
Not Available	23.5%	22.3%	23.5% [19.8% - 27.6%]
Geography (Core Based Statistical Area)			
Division	14%	14.9%	14.0% [11.5% - 16.9%]
Metropolitan	41.4%	48.7%	41.4% [37.3% - 45.7%]
Micropolitan	18.9%	21.2%	18.9% [15.8% - 22.4%]
Rural	25.7%	15.2%	25.7% [21.4% - 30.5%]
Critical Access Hospital			
Yes	29.6%	14.8%	29.2% [24.6% - 34.2%]
No	70.2%	85.3%	70.8% [65.8% - 75.4%]
Teaching Status			
Yes	26.3%	31.9%	26.3% [23.0% - 30.0%]
No	73.7%	68.1%	73.7% [70.0% - 77.0%]
Bed Size			
Up to 99	49.4%	35.0%	49.4% [44.9% - 53.8%]
100 to 399	40.4%	51.7%	40.4% [36.4% - 44.6%]
400 or more	10.2%	13.3%	10.2% [8.3% - 12.5%]
Medicare Discharges			
4 th Quartile (highest)	25%	10.0%	25% [20.4% - 30.2%]
3 rd Quartile	25%	23.7%	25% [21.5% - 28.8%]
2 nd Quartile	25%	35.1%	25% [21.9% - 28.4%]
1 st Quartile	25%	31.2%	25% [21.9% - 28.5%]

Source: AHA-FAH Drug Survey; 2014 AHA Annual Survey

To identify the drugs that had the greatest impact on hospital budgets due to changes in price and not volume, we analyzed the GPO data containing information on spending, price, and volume for the 28 selected drugs over a three-year period (CY2013 to CY2015). Total spending and pricing information was aggregated across dosage/strength combinations and branded/generic versions for each drug.¹⁷ We then identified the 10 drugs that had the highest total inpatient drug spending by the GPOs during CY2015, and computed growth in total spending and unit price for these drugs. We also identified the 10 drugs with the largest unit price growth between 2013 and 2015. As shown in Table 3, compared to all U.S. community hospitals, a larger proportion of GPO hospitals were for-profit; belonged to a hospital system; were located in an urban setting; were not a critical access hospital; were designated as teaching hospitals; and were larger in size in terms of number of beds. The GPO hospital sample is a convenience sample; in other words, no sampling weights are used. Because the information from the GPOs was aggregated, we could not apply post-stratification weighting. However, as shown in Table 3, on aggregate, the characteristics of GPO hospitals are quite similar to that of all U.S. community hospitals.

¹⁷ Prices are inclusive of all discounts, including those offered as volume based discounts as well as those rebates offered for drugs of varying market competitiveness and relative efficacy.

Table 3. Key Characteristics of Sampled GPO Hospitals Compared to all U.S. Community Hospitals

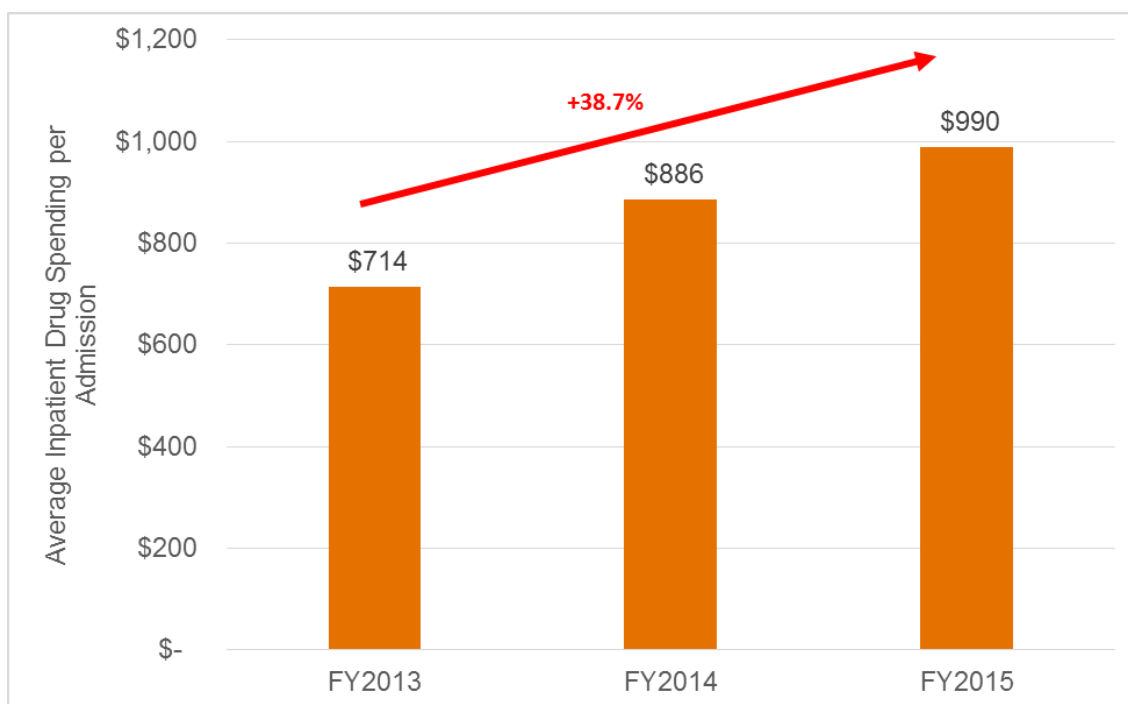
Hospital Characteristic	All Community Hospitals	Community Hospitals Belonging to the Two GPO Networks
Number of Hospitals	4,369	More than 1,400
Ownership		
Government	22.5%	19.2%
Not-for-profit	61.8%	64.3%
For-profit	15.6%	16.5%
Hospital System		
Yes	60.9%	67.1%
No	39.1%	32.9%
Geography (Core Based Statistical Area)		
Division	14%	11.4%
Metropolitan	41.4%	45.8%
Micropolitan	18.9%	22%
Rural	25.7%	20.9%
Critical Access Hospital		
Yes	29.6%	24.6%
No	70.2%	75.4%
Teaching Status		
Yes	26.3%	31.2%
No	73.7%	68.8%
Bed Size		
Up to 99	49.4%	46.4%
100 to 399	40.4%	40.7%
400 or more	10.2%	12.9%
Medicare Discharges		
4 th Quartile (highest)	25%	18.7%
3 rd Quartile	25%	27.4%
2 nd Quartile	25%	25.8%
1 st Quartile	25%	28.1%

Source: 2014 AHA Annual Survey; GPO Rx Data

KEY FINDINGS

Inpatient drug spending increased significantly between FY2013 and FY2015. Average annual inpatient drug spending at U.S. community hospitals increased by 23.4 percent between FY2013 and FY2015 (from \$5.2 million to \$6.5 million).¹⁸ Over the same period, average inpatient drug spending increased 38.7 percent on a per admission basis (from \$714 to \$990, see Figure 1).¹⁹

Figure 1. Inpatient Drug Spending per Admission Has Increased Substantially Since 2013



Source: AHA-FAH Drug Survey; 2012-2014 AHA Annual Survey

¹⁸ Average annual spending was estimated to increase 11.5 percent between FY2013 and FY2014 from \$5.2 million to \$5.8 million. Between FY2014 and FY2015, average annual spending increased by 10.7 percent to \$6.5 million.

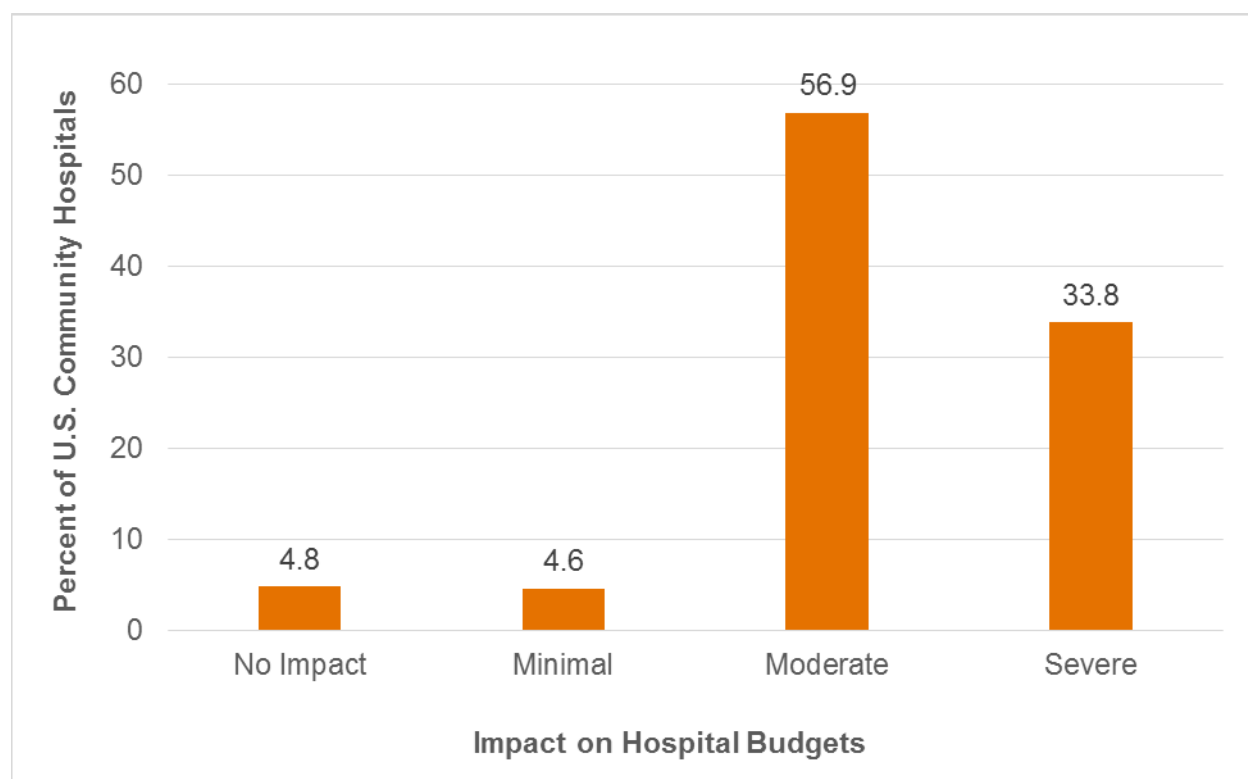
¹⁹ On a per-admission basis, average inpatient drug spending was estimated to be \$714 during FY2013. Between FY2013 and FY2014, spending increased by 24 percent to \$886 [\$795 - \$976]. Between FY2014 and FY2015, spending increased by 12 percent to \$990 [\$893 - \$1086].

Changes in inpatient drug spending impacted hospitals' ability to manage costs within a fixed payment system between FY2013 and FY2015. Over 90 percent of the hospitals responding to the Drug Survey reported that recent changes in drug prices had a moderate or severe impact on their budgets, with a third of hospitals rating the impact as "severe" (Figure 2). These observations are reinforced by the fact that growth in inpatient drug spending during this period exceeded the Medicare

"There might be upgrades you were trying to do, but there is only [so much] budget to do those things. Is it mandated? Can we duct tape this equipment? If it breaks in six months, we'll buy it out of contingency. These are the tough choices that a small community hospital needs to make.... Drug volume has gone down while dollars [prices] have gone up.... We'll do anything to drive costs down, even [cut] costs like gas and electricity. It's really like a household budget."
 -- Pharmacy Administrator

hospital rate update (IPPS market basket plus/minus adjustments), the pharmaceutical price inflation rate, as well as the spending in the retail drug market (Figures 3 and 4).²⁰

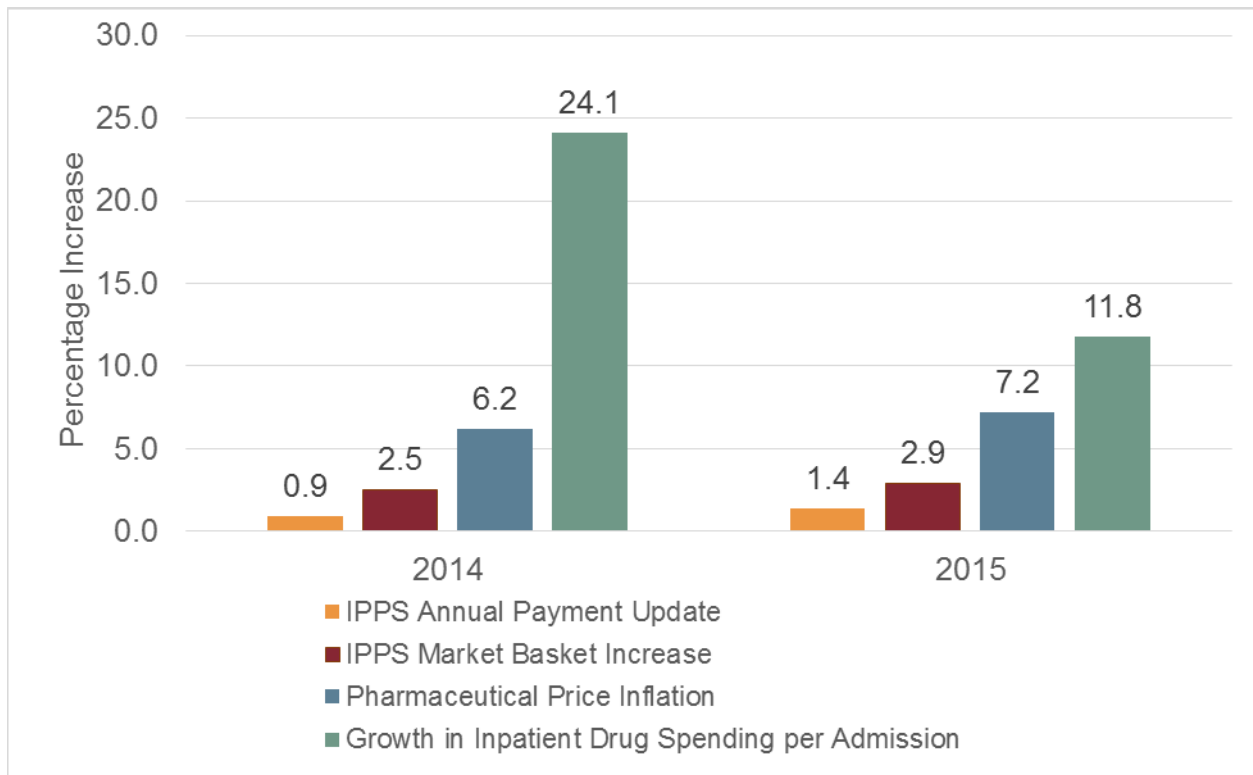
Figure 2. Over 90% of Hospital Administrators Reported That Higher Drug Prices Had a Moderate or Severe Impact on Their Budgets



Source: AHA-FAH Drug Survey

²⁰ Medicare payments are adjusted annually based on changes to the cost of goods and services ("market basket") plus or minus any other adjustments as a result of other policy changes, such as coding adjustments.

Figure 3. Growth in Inpatient Drug Spending Has Far Outpaced Payer Reimbursement and Pharmaceutical Price Inflation

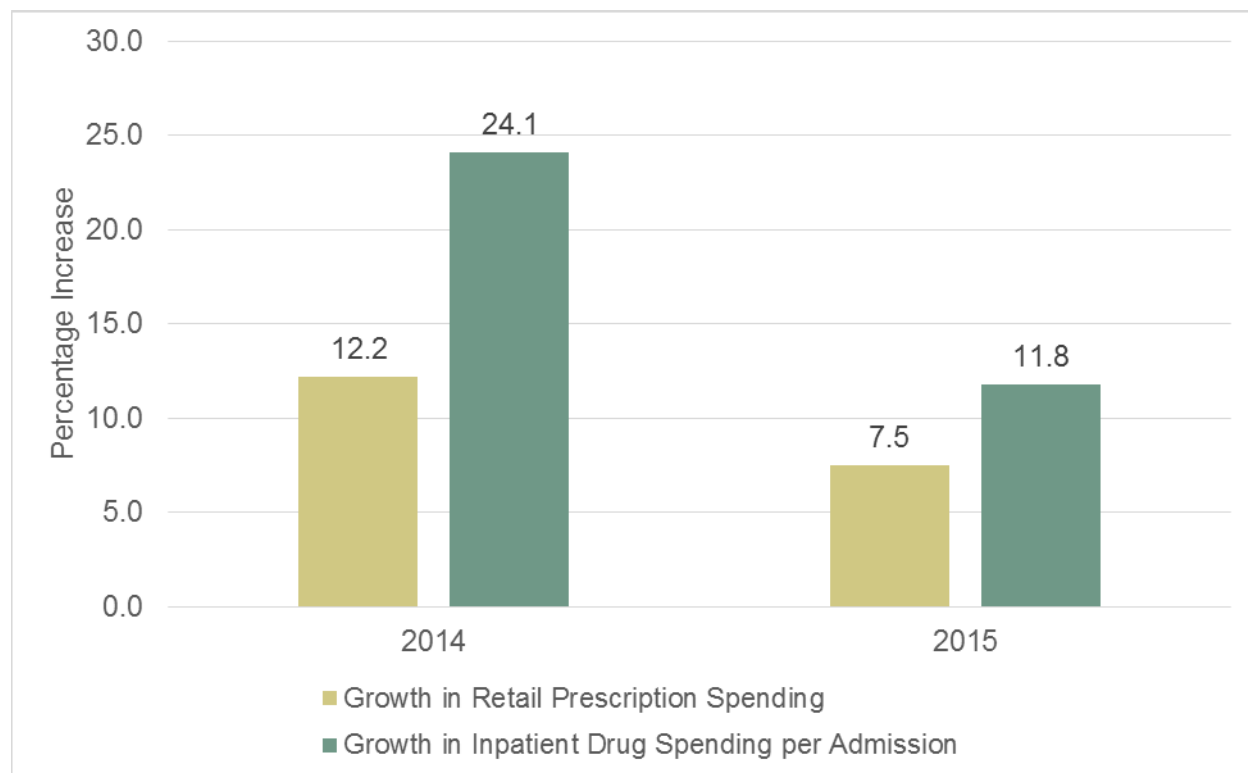


Source: CMS, Bureau of Labor Statistics, National Health Expenditure Data, AHA-FAH Drug Survey

Note: Pharmaceutical Price Inflation refers to the pharmaceutical preparation manufacturing Producer Price Index. Alternative measures include the pharmaceutical indexes for the Consumer Price Index (CPI) and the Import/Export Price Index (IPP).

Note: Adding growth in annual inpatient drug spending per admission in FY2014 and FY2015 (i.e. 24.1% + 11.8%) will not equal the compounded growth rate during the two period (38.7%)

Figure 4. Inpatient Drug Spending Growth Eclipsed Retail Prescription Drug Spending Growth



Source: CMS, Bureau of Labor Statistics, National Health Expenditure Data, AHA-FAH Drug Survey

Note: Data for the 2015 retail prescription price increase is provided by DHHS Office of the Assistant Secretary for Planning and Evaluation (ASPE) projections of NHE data. Medical inflation refers to medical component of the CPI (Consumer Price Index).

Note: Adding growth in annual inpatient drug spending per admission in FY2014 and FY2015 (i.e. 24.1% + 11.8%) will not equal the compounded growth rate during the two period (38.7%)

Drug price increases had a larger impact on hospital drug spending than utilization between CY2013 and CY2015. The data from the two GPOs included information on total inpatient spending, unit price, and change in unit price between CY2013 and CY2015 for the selected drugs. From this data, we were able to calculate total utilization for each year and evaluate how utilization changed over the three year period. By comparing changes in drug prices and changes in utilization on total spend for a drug, we were able to identify where spending was more significantly impacted by price or volume. Consistently, changes in prices drove increases in spending. Figure 5 and Appendix Table A.1 presents information for the 10 drugs with the highest spending; Figure 6 and Appendix Table A.2 presents information for the 10 drugs with the greatest change in unit cost.

Drug price increases appear to be random and inconsistent from one year to the next. The unit price of many of the drugs changed significantly and unpredictably. Many of these drugs – but not all – were high-volume drugs (e.g., calcitonin, nitroprusside, isoproterenol, neostigmine methylsulfate, pytonadione, and glycopyrrolate; Figures 5 and 6). Most were not innovator drugs, that is, brand name

drugs under patent protection. While some drugs increased at similar rates each year (e.g., glucagon), others varied dramatically one year to the next (e.g., acetaminophen, calcitonin).

The rationale for changes in price is not immediately clear. For some, it appears that the instigator for the price change was simply a change in the drug’s ownership. For example, the leukemia drug Oncaspar (pegaspargase) was originally approved in 1994. The price of the drug increased by nearly \$10,000 last year after Baxalta Inc.’s purchase. The antiparasitic Daraprim (pyrimethamine) was originally approved in 1953, yet cost hospitals substantially more in CY2015 after new owner Turing Pharmaceuticals increased the price by more than 3,000 percent. As previously noted, Valeant increased the prices of Isuprel and Nitropress by hundreds of percent between CY2013 and CY2015 after they purchased the rights to those drugs from Marathon Pharmaceuticals.²¹

“You can pretty much ballpark medications that were already high priced, but it’s for the ones that were \$5 last year and \$300 this year. Those are the ones that make it very difficult to budget. These types of increases are being more commonly found for generics. It used to be you could buy these generics and save, now all of a sudden these generics are not cheap anymore. For Isuprel, which is in all your crash carts and increased 500 percent overnight, there is no way to budget ahead of time. It’s taking up pretty much the entire DRG reimbursement on cases.”
 -- Pharmacy Vice President

We did a presentation on nitroprusside and other old drugs to our CEO and our executive team. Our CEO was a former surgeon so he was familiar with the drug. He couldn’t believe the magnitude of the increases - he knew it’s been around forever.”
 -- Chief Pharmacy Officer

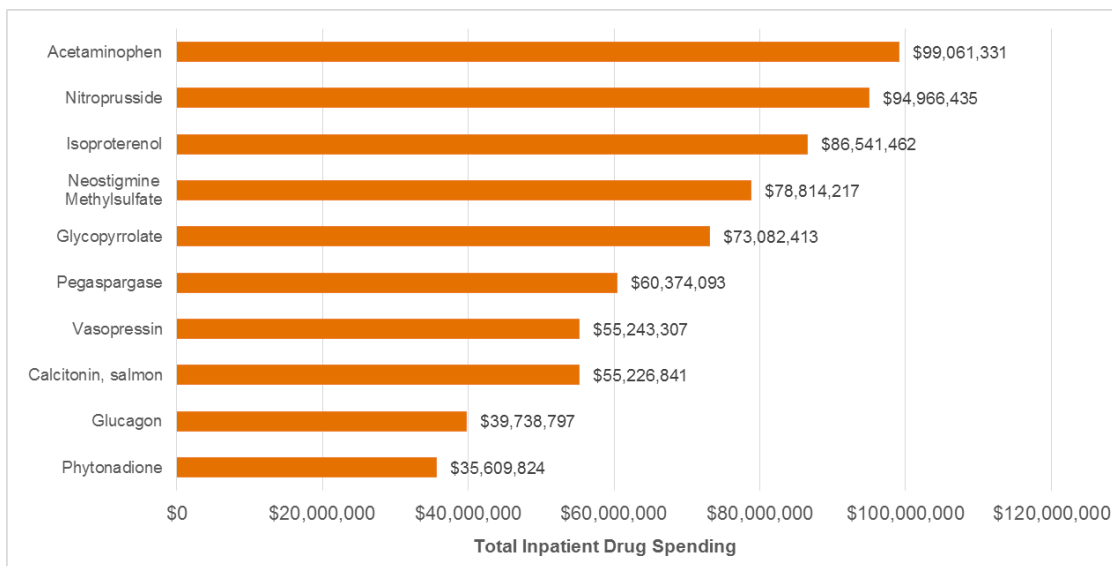
Temporary market failures also appear to impact drug pricing, sometimes with lasting consequences. In 2012 Luitpold Pharmaceuticals, one of only two makers of glycopyrrolate (a drug used to dry secretions prior to surgery) temporarily closed its factory to fix quality control problems.²² Hikma Pharmaceuticals, the other manufacturer, then raised its prices of the injectable version in 2013. As a result, GPOs experienced a 334 percent increase in the drug’s price in CY2014. However, once both manufacturers were making it again, its price decreased by just 5 percent in CY2015.

²¹ These figures still reflect aggregated GPO data and represent the price change across two years, see Table A.2.

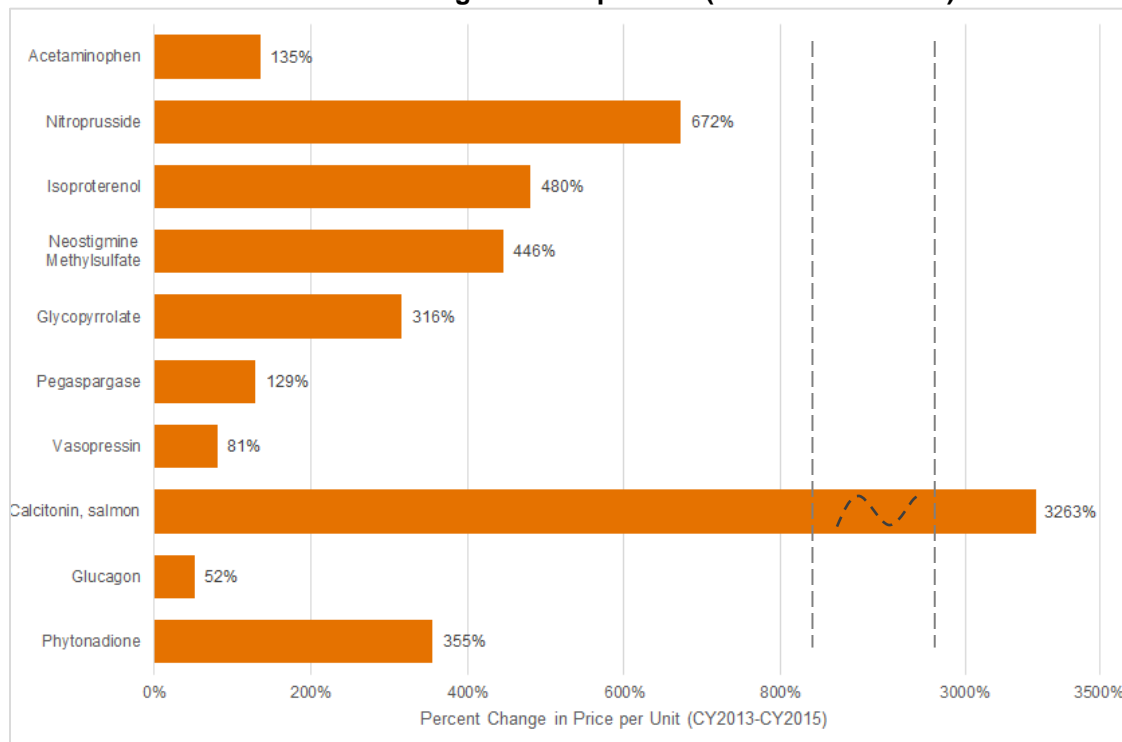
²² Cynthia Koons, "Broken Markets for Old Drugs Means Price Spikes Are Here to Stay," *Bloomberg*, November 18th, 2015, <http://www.bloomberg.com/news/articles/2015-11-18/the-law-of-pharma-pricing-physics-what-goes-up-often-stays-up>.

Figure 5. Drugs with the Highest Spending Experienced Significant Price Increases in 2014 and 2015

5.a. Total Inpatient Spending (CY2015)



5.b. Percent Change in Price per Unit (CY2013 to CY2015)

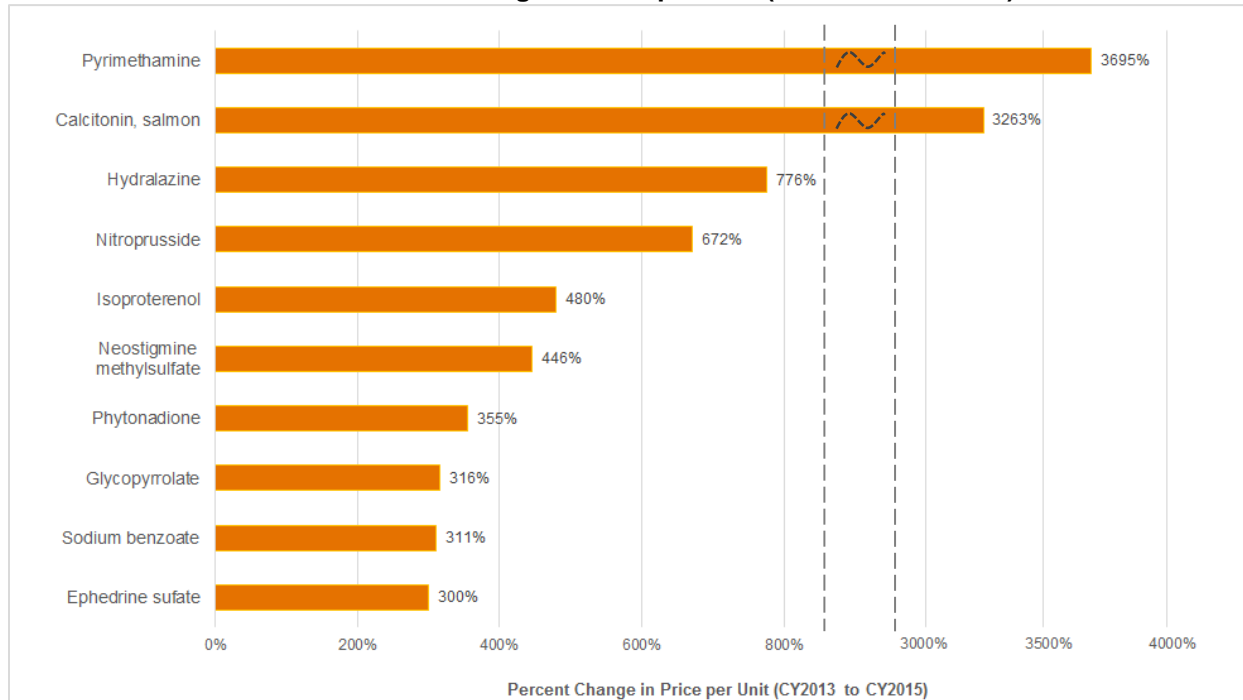


Source: GPO Rx Data

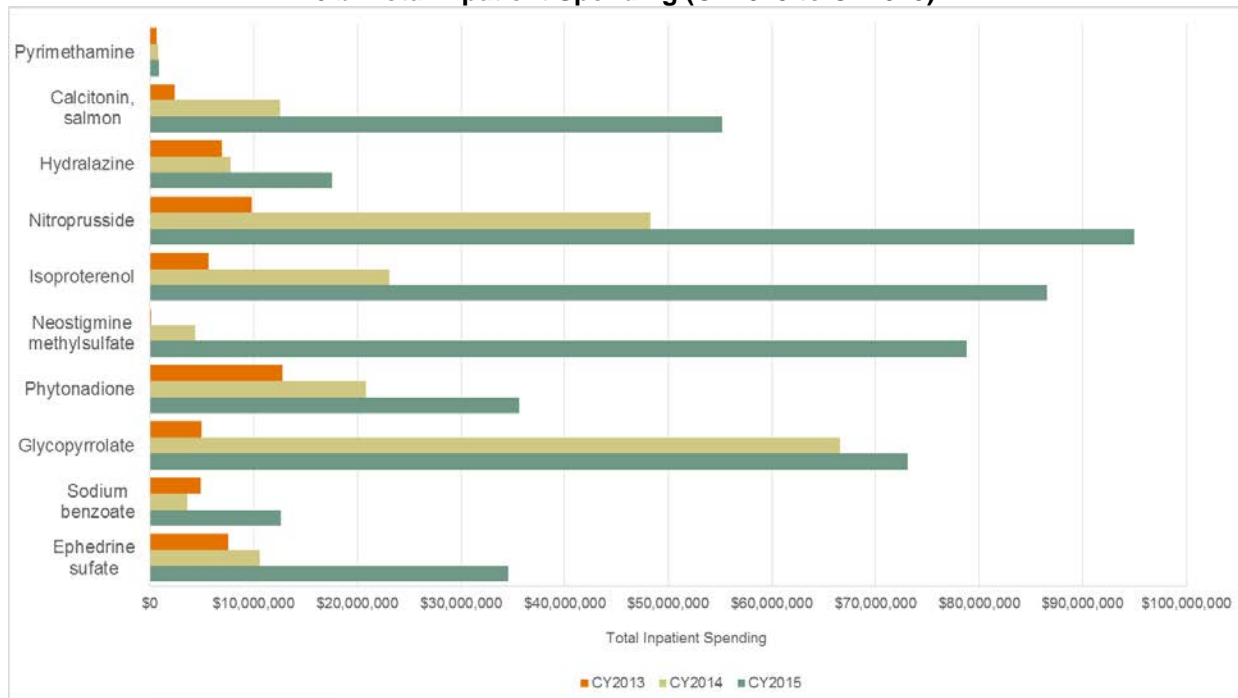
Note: Spending and price increases do not necessarily correlate exactly due to changes in volume. In other words, a 100 percent price increase may not result in a 100 percent spending increase due to changes in patient mix, prescribing patterns, and whether the hospital was able to find an alternative drug.

Figure 6. Drugs with the Highest Price Increases between 2013 and 2015 Also Experienced Significant Spending Increases

6.a. Percent Change in Price per Unit (CY2013 to CY2015)



6.b. Total Inpatient Spending (CY2013 to CY2015)



Source: GPO Rx Data

Note: Spending and price increases do not necessarily correlate exactly due to changes in volume. In other words, a 100 percent price increase may not result in a 100 percent spending increase due to changes in patient mix, prescribing patterns, and whether the hospital was able to find an alternative drug.

CONCLUSIONS

This study examines trends in inpatient drug spending for hospitals nationwide in order to determine the quantitative impact and to discover how such changes may have impacted hospitals' ability to manage costs. Findings show:

- Drug spending in the hospital inpatient setting is quickly increasing. Growth in annual inpatient drug spending between FY2013 and FY2015 increased on average 23.4 percent, and on a per admission admission basis, 38.6 percent. Growth in spending in the inpatient setting exceeded the growth in retail spending, which increased 9.9 percent during this period. In contrast, CMS's update to hospital rates through the IPPS increased by only 2.7 percent. Large and unpredictable increases in the price of drugs used in the inpatient setting significantly impacted hospitals' ability to manage costs within a fixed price based payment system.
- Many of the sampled drugs that accounted for a substantial proportion of total inpatient drug spending experienced dramatic unit price increases in CY2014 and CY2015. In most cases, the identified top ten drugs were not new entrants.²³ About half of the 28 drugs had no active generic competition, leaving hospitals no lower cost alternatives. For most of the drugs, growth in unit price – not volume – was primarily responsible for the increase in total inpatient drug spending.
- Stakeholder interviews suggest that significant budgetary accommodations are needed to keep up with rising drug prices. Most of those interviewed raised concerns about older generic drugs whose prices have increased unpredictably and the lack of alternatives available in order to provide high quality care to their patients.

²³ The drugs received FDA approval prior to CY2013.

Limitations

The conclusions of this study should be considered in the context of the following limitations:

- The information on total spending for inpatient drugs between FY2013 and FY2015 gathered from the Drug Survey was self-reported.
- Of the 4,369 hospitals that met the criteria to participate in the survey, only 778 responded and the data from only 712 was sufficiently clean to be used.
- Although the survey solicited responses from individual hospitals, some hospitals systems reported aggregate information for the entire system. The analysis took account such responses where it was readily evident that the response was at the system level.
- Not all hospitals participate in GPOs (the GPO data include information on 1,409 of 4,369 U.S. community hospitals), which allow hospitals to consolidate their collective purchasing power. As such, the GPO data may not be reflective of the experience of all hospitals, and likely understates the actual rate of growth.

APPENDIX

Table A1. Change in Unit Cost for Top Ten Drugs with Highest Total Spending in CY2015 (GPO Data)

Generic name	Total Inpatient Spending CY2013	Total Inpatient Spending CY2014	Total Inpatient Spending CY2015	Unit Price CY2013	Unit Price CY2014	Unit Price CY2015	Percent Change in Unit Price (CY2013 - CY2014)	Percent Change in Unit Price (CY2014 - CY2015)
Acetaminophen	43,156,542.02	87,113,521.07	99,061,331.23	12.94	27.64	30.46	114%	10%
Nitroprusside	9,802,140.32	48,278,606.78	94,966,434.83	102.34	150.31	790.46	47%	426%
Isoproterenol	5,602,447.81	23,066,826.13	86,541,461.54	278.67	804.16	1,617.62	189%	101%
Neostigmine methylsulfate	56,818.46	4,311,153.48	78,814,217.26	15.69	16.44	85.59	5%	421%
Glycopyrrolate	4,932,748.72	66,606,577.06	73,082,412.98	5.46	23.83	22.70	337%	-5%
Pegaspargase	32,142,583.64	34,337,561.15	60,374,093.00	5,605.44	5,617.24	12,858.14	0%	129%
Vasopressin	1,923,293.58	3,698,147.36	55,243,306.86	-	48.76	88.16	-	81%
Calcitonin, salmon	2,372,551.94	12,529,284.26	55,226,841.19	67.98	923.51	2,286.23	1259%	148%
Glucagon	23,427,876.25	26,041,923.88	39,738,796.65	109.66	132.91	166.80	21%	25%
Phytonadione	12,731,141.91	20,809,335.38	35,609,824.48	549.84	1,241.61	2,502.80	126%	102%

Source: GPO Rx Data

Table A2. Top Ten Drugs with Highest Unit Price Increases in CY2015 (GPO Data)

Generic name	Total Inpatient Spending CY2013	Total Inpatient Spending CY2014	Total Inpatient Spending CY2015	Unit Price CY2013	Unit Price CY2014	Unit Price CY2015	Percent Change in Price per Unit (CY2013 - CY2015)
Pyrimethamine	595,748.81	801,690.28	812,109.32	919.10	1,045.52	34,882.24	3695%
Calcitonin, salmon	2,372,551.94	12,529,284.26	55,226,841.19	67.98	923.51	2,286.23	3263%
Hydralazine	6,951,150.65	7,725,372.30	17,568,936.99	4.72	5.02	41.32	776%
Nitroprusside	9,802,140.32	48,278,606.78	94,966,434.83	102.34	150.31	790.46	672%
Isoproterenol	5,602,447.81	23,066,826.13	86,541,461.54	278.67	804.16	1,617.62	480%
Neostigmine methylsulfate	56,818.46	4,311,153.48	78,814,217.26	15.69	16.44	85.59	446%
Phytonadione	12,731,141.91	20,809,335.38	35,609,824.48	549.84	1,241.61	2,502.80	355%
Glycopyrrolate	4,932,748.72	66,606,577.06	73,082,412.98	5.46	23.83	22.70	316%
Sodium benzoate	4,857,185.90	3,559,993.22	12,651,343.86	11,118.66	5,192.88	45,665.71	311%
Ephedrine sulfate	7,533,234.15	10,528,689.87	34,552,474.48	5.98	8.90	23.96	300%

Source: GPO Rx Data

Table A3. Glossary

Generic Name	Therapeutic Class	Medical Use	Approval in Past Four Years	Any Generic Competition
Acetaminophen	Analgesic	Treats minor aches and pains, and reduces fever	No	Yes
Calcitonin, salmon	Calcitonin	Treats bone pain and other symptoms of Paget's disease, hypercalcemia, and osteoporosis	No	Yes
Ephedrine sulfate	Sympathomimetics; decongestants, vasopressors	Used to prevent low blood pressure during spinal anesthesia	No	Yes
Glucagon	Hormone, hyperglycemic agent	Treats severe low blood sugar	No	Yes
Glycopyrrolate	Synthetic anticholinergic	Reduces secretions in the mouth, throat, airway and stomach before surgery	No	Yes
Hydralazine	Vasodilator, arteriolar vasodilator	Direct-acting smooth muscle relaxant used to treat high blood pressure	No	Yes
Isoproterenol	Nonselective beta-agonist; sympathomimetic	Used to improve breathing while a patient is under anesthesia, or to treat certain types of heart problems	No	No
Neostigmine methylsulfate	Antianginal, antihypertensive	Reversal agent of certain kinds of muscle relaxants used in surgery	May 31st, 2013 Approval	No
Nitroprusside	Vasodilator	Used to treat congestive heart failure and life threatening high blood pressure, or to keep blood pressure low during a surgery	No	No
Pegaspargase	Chemotherapy, asparaginase	Leukemia treatment	No	No
Phytonadione	Vitamin K	Aids blood clotting	No	Yes
Pyrimethamine	Antiparasitic, antimalarial agent	Treats toxoplasmosis, can also prevent malaria and other infections	No	No
Sodium benzoate	Metabolic Agent	Treatment of urea cycle disorders and hyperammonemia	No	Yes
Vasopressin	Hormone, vasoconstrictor	A blood vessel constricting agent used in emergencies, also used to treat diabetes insipidus, after stomach surgery or before stomach x-rays	April 17th, 2014 Approval	Yes

The U.S. health care system is facing a prescription drug spending crisis fueled by staggering increases in the price of drugs. While the need and potential for the development of innovative drug therapies is large, the dramatic increases in the price of both new and existing drugs threatens to make them inaccessible to patients and the providers who care for them. In a recent survey conducted by the American Hospital Association (AHA) and the Federation of American Hospitals (FAH) and analyzed by NORC at the University of Chicago, hospitals reported that spending on inpatient drugs increased by 24 percent per admission in 2014 and 12 percent per admission in 2015.¹ These increases were due to drugs like hydralazine, a drug used in hospital settings to manage blood pressure, and neostigmine methylsulfate, a neuromuscular blocking agent used after surgery. In 2015, the cost of hydralazine jumped 723 percent, while the cost of neostigmine methylsulfate rose by 421 percent.² As a result, more than 90 percent of hospital administrators report moderate to severe challenges in managing hospital budgets within the fixed reimbursement inpatient payment model.

The AHA is deeply committed to the availability of high-quality, efficient health care for all Americans. Hospitals, and the clinicians who work in them, know firsthand the lifesaving potential of drug therapies. Indeed, researchers in U.S. academic medical centers generate much of the evidence used to develop new drugs. However, an unaffordable drug is not a lifesaving drug.

Over the past 12 months, the AHA has worked with its members to document the challenges hospitals and health systems face with drug prices and develop policy solutions to protect access to critical therapies while encouraging and supporting much-needed innovation. The following policy recommendations, approved by the AHA Board of Trustees, were surfaced by the AHA's work with the Campaign for Sustainable Rx Pricing. The recommendations, detailed below, support the following overarching goals with respect to drug pricing:

- 1) Increased competition and innovation
- 2) Increased transparency
- 3) Payment for value
- 4) Improved access
- 5) Alignment of incentives

INCREASE COMPETITION & INNOVATION

Competition for prescription drugs generally results in increased options for lower cost therapies, particularly through the introduction of one or more generic competitors. These proposals seek to increase the introduction of generic alternatives and discourage anti-competitive tactics while maintaining incentives for the development of innovative new therapies.

¹ AHA/FAH Drug Survey 2016

² AHA/FAH Drug Survey 2016

- **Fully resource Food and Drug Administration (FDA) review and approval offices.** FDA has a significant backlog of both generic and branded drug applications. While a number of fast-track programs exist, FDA does not have the resources available to process applications in a timely manner. Under this proposal, Congress would appropriate additional resources to FDA specifically for purposes of hiring personnel to process applications.
- **Fast-track generic applications when no or limited generic competition exists.** Generic competition is critical to a functioning drug marketplace. Research suggests that optimal pricing is achieved when there are five or more generic manufacturers competing on the same drug.³ In order to encourage additional generic entrants to the market, this proposal would require FDA to prioritize review of applications where there is no generic option available or in instances of a drug shortage. While FDA voluntarily decided earlier this year to prioritize generic applications for drugs without generic competition, this policy proposal would codify this approach in federal law with statutory deadlines for review.
- **Incentivize generic manufacturers with fast-track voucher rewards.** In order to further promote the introduction of generic drugs, this policy would reward generic manufacturers that have a drug approved under the above process with a voucher to fast-track any other generic application.
- **Deny patents for “evergreened” products.** Some drug manufacturers attempt to minimize or eliminate competition through product “evergreening.” A manufacturer attempts to “evergreen” a product when it applies for patent and market exclusivity protections for a “new” product that is essentially the same as the original product, such as extended release formulations or combination therapies that simply combine two existing drugs into one pill. What generally happens is that, while the older version of the drug is no longer patent-protected and, therefore, generic alternatives may be offered, drug manufacturers promote the newer version as the “latest and greatest.” Without important information on the comparative value of the newer drug, many providers and consumers switch to the brand-only “evergreened” product assuming that the newer version is superior. This policy proposal would deny patents for products that are simply modifications of existing products unless the new product offers significant improvements in clinical effectiveness, cost savings, access or safety.
- **Deem “pay-for-delay” tactics to be presumptively illegal and increase oversight.** Some brand drug manufacturers pay generic manufacturers to delay entry into the market. In 2013, the U.S. Supreme Court ruled that such deals could be a violation of antitrust law, but declined to declare them presumptively illegal. Subsequently, the

³ MedPAC, based on FDA analysis of retail sales data from IMS Health, IMS National Sales Perspective, 1999-2004, as analyzed by Jack Hoadley, Ph.D., Health Policy Institute, Georgetown University, for the Bipartisan Policy Center, April 13, 2016. Accessible at: <http://cdn.bipartisanpolicy.org/wp-content/uploads/2016/03/Hoadley-BPC.pdf>

Federal Trade Commission (FTC) has reported a significant decrease in pay-for-delay deals but an increase in other “settlements” between brand and generic manufacturers. This policy proposal would clarify in federal law that such practices are presumptively illegal and increase FTC resources to investigate these and other settlements.

- **Limit orphan drug incentives to true orphan drugs.** Drug manufacturers receive a number of incentives to develop drugs for rare diseases. These incentives, which include waived FDA fees, tax credits and longer market exclusivity periods, are intended to spur innovation of therapies for which the manufacturer may otherwise not recoup their investment due to low volume. These incentives have contributed to the development of innovative, life-saving drugs where no therapies previously existed. However, in some instances, manufacturers have received orphan drug status for drugs that they subsequently marketed for other, non-rare indications. In these instances, manufacturers are receiving the incentives for drugs that are broadly used. This proposal would direct FDA to collect information on other intended indications for the drug when evaluating eligibility for orphan drug status. It also would direct FDA to do a post-market review at regular intervals throughout the market exclusivity period to determine whether the drug should retain its status as an orphan drug. In instances where the manufacturer is promoting the drug for other indications that do not meet the orphan drug status requirements, FDA could levy penalties, such as requiring that the manufacturer pay the government back the value of the tax breaks and waived fees and potentially reducing the market exclusivity period.
- **Investigate potential abuses of the Risk Evaluation and Mitigation Strategies (REMS) program.** Some drug manufacturers inaccurately claim as part of the REMS program that certain drugs come with such significant risks that it is not safe to allow generic manufacturers access to samples for purposes of bioequivalency testing. This practice inappropriately stifles competition by preventing the generic manufacturer from obtaining sufficient quantities of the drug for testing and duplication, therefore, ensuring that the branded version of the drug remains the only option available. This proposal would require FDA to evaluate the use of REMS and issue a report on its findings, including whether manufacturers are using REMS protections to inhibit generic manufacturer access to samples and develop recommendations for increased oversight and enforcement.
- **Disallow co-pay assistance cards.** Some drug manufacturers offer co-pay assistance cards to encourage patients to request certain higher-cost drugs. While these cards may lower patients’ out-of-pocket costs for certain high-priced drugs, they have a number of negative consequences that drive up overall costs for patients and the health care system. These cards often inappropriately steer patients to higher cost drugs rather than cheaper alternatives. They also disrupt insurance plan design by enabling consumers to use the value of the card to more quickly reach out-of-pocket maximums. As a result, patients appear to be shielded from the cost of the drugs. However, insurers facing substantial increases in prescription drug costs must raise consumer premiums to cover the cost of

the drug. This proposal would prohibit drug manufacturers from using co-pay cards as a patient inducement.

INCREASE TRANSPARENCY

Payers, providers and the public have little information about how drugs are priced. This gap in information challenges payers' abilities to make decisions regarding coverage and pricing of drugs, and often results in mid-year cost increases that providers are unprepared to manage. These policy proposals seek greater parity between drug manufacturers and other sectors of the health care system, including hospitals, which already disclose a considerable amount of information on pricing, input costs and utilization.

- **Increase disclosure requirements related to drug pricing, research and development at the time of application for drug approval.** There is very little evidence of what it actually costs to develop a new drug and how those costs factor into the pricing of a drug. Other components of the health care system are held to a much higher transparency standard. For example, hospitals provide detailed data to the Centers for Medicare & Medicaid Services (CMS) via the annual Medicare cost report, which includes information on facility characteristics, utilization, costs and charges, and financial data. Given the significant taxpayer investment in drugs – both through funded research and purchasing through public programs like Medicare and Medicaid – there should be greater transparency parity between drug manufacturers and other health care providers.

Increased transparency into drug pricing could be used to hold drug manufacturers accountable for fairly pricing products, help calculate the value of a drug, and support future policymaking. Under this policy proposal, drug manufacturers would be required to submit as part of the drug approval process information on anticipated product pricing for both a single unit and a course of treatment; anticipated public spending on the product (e.g., from government purchasers including Medicare, Medicaid and TRICARE, among others); and information on how the product was priced, including anticipated portion of the product price that will contribute to current or future marketing and research and development costs. Drug manufacturers also would be required to provide information on the research that contributed to the development of the drug.

Manufacturers would need to specify all entities that conducted research that contributed to the development of the drug, the amount spent on that research and the funding source.

- **Issue consumer and provider-facing annual reports on drug pricing.** Recently, CMS began publicly reporting on the costs associated with 80 drugs covered by either Medicare Part B or Part D benefits.⁴ CMS selects the drugs based on whether they are in the top 15 in total program spending, high annual cost per user or annual cost increase. While this is an important first step, the data are not presented in an easy-to-use format

⁴ https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Dashboard/Medicare-Drug-Spending/Drug_Spending_Dashboard.html

for patients or providers. This policy proposal would expand CMS's reporting on drug costs and spending to the Medicaid program and require the agency to issue consumer and provider-friendly reports on an annual basis. Such information will help providers and consumers make informed decisions about preferred drugs, and will help hold drug manufacturers accountable for their initial launch prices and price changes over time.

PAY FOR VALUE

The health care system is reorienting toward value. While significant strides have been made in developing value-based payment (VBP) models for hospitals and physicians, little work has been done on drug purchasing models. These proposals would advance the development and implementation of such arrangements for drugs.

- **Develop Medicare-negotiated VBP arrangements.** Most health care providers are participating in some form of VBP through which reimbursement is based, at least in part, on health outcomes, efficiency and quality. While considerable work already has been done in the development of VBP models for providers, very few models exist for pharmaceutical drugs. There are several exceptions. For example, Harvard Pilgrim and Amgen have implemented an outcomes-based payment model for a cholesterol drug;⁵ and Eli Lilly and Anthem are working together to develop outcomes-based contracts for drugs.⁶

Under this proposal, CMS would take a leading role in developing demonstration programs through its Center for Medicare & Medicaid Innovation to test VBP models for drugs purchased under all parts of Medicare. Specifically, we recommend that CMS undertake a public, multi-stakeholder process to develop potential VBP models for drugs. This process would begin with an initial meeting between CMS and a broad group of stakeholders to discuss the scope of potential demonstration projects (e.g., limited to Parts B or D, condition-specific, etc.) and potential VBP models for consideration. Subsequently, CMS would issue a request for information for more details on specific proposals. Based on this information, CMS would follow the standard regulatory process for proposing, modifying and finalizing VBP models for testing. Drug purchasers, including hospitals, could use these CMS-developed models in negotiations with manufacturers for other populations as well.

Examples of potential VBP models include:

- **Indications-based pricing.** This model would vary the payment for a drug based on its clinical effectiveness for the different indications for which it has been approved. CMS would use evidence from published studies and reviews, such as those issued by the Institute for Clinical and Economic Review (ICER), or

⁵ Herman, Bob, "[Harvard Pilgrim cements risk-based contract for pricey cholesterol drug Repatha](#)," Modern Healthcare, November 9, 2015.

⁶ Eli Lilly and Anthem, "[Promoting Value-Based Contracting Arrangements](#)," January 2016

evidence-based clinical practice guidelines that are competent and reliable. The AHA recognizes that additional work would be needed to determine the clinical effectiveness of particular drugs for their various indications. Furthermore, CMS would need to consider the information systems requirements. For example, hospitals' electronic health records would need to be able to easily link a particular drug to the indication for which it was prescribed. However, this approach should be further explored recognizing that the additional work required will take time to complete.

- **Risk-sharing agreements based on outcomes.** This model would link the price of a drug with patient health outcome goals. The outcome-based agreements would tie the final price of a drug to results achieved by specific patients rather than using a predetermined price based on historical population data. Manufacturers would agree to provide rebates, refunds or price adjustments if the product does not meet targeted outcomes. In exploring this option, CMS would need to evaluate potential technological, programmatic and operational challenges that hospitals may face, such as agreeing to common outcome metrics and tracking them via hospital information systems.
- **Develop a comparative effectiveness evidence base.** We have little data on how different treatments perform relative to other treatments in their class. This information is critical to supporting providers in making care decisions, helping payers make coverage decisions and develop value-based purchasing models, and support policymakers in evaluating and advancing appropriate drug policy. While some of this work is being done by the government, such as through the Patient-Centered Outcomes Research Institute, and through private-sector initiatives, more must be done to collect and centralize this information. This proposal would require drug manufacturers to submit to FDA a dossier of comparative effectiveness research as part of the drug approval process, something that already is required by other countries as part of their drug review and approval processes. FDA would make this information publicly available and would serve as a starting point for assessing the value of an individual drug.
- **Align payment with the most commonly used dosage.** Many common medications are packaged in sizes that do not align with the most common dosages. Frequently, too much medication is included in the package, resulting in waste when a provider discards the now potentially tainted remaining content. One study found that packaging size alone results in \$3 billion of wasted cancer drugs each year.⁷ In this proposal, CMS would require drug manufacturers selling products that are used for Medicare and Medicaid beneficiaries to package drugs in the most common dosage or face reduced reimbursement. For example, if the most common dosage of a drug is 10ml but the drug is sold in 15ml vials only, the drug manufacturer would be required to provide a rebate for the portion of the drug above the common dosage amount unless the purchaser

⁷ Bach, P. et al, "[Overspending driven by oversized single dose vials of cancer drugs](#)," BMJ, March 1, 2016

specifically requests a different amount. This proposal would incentivize manufacturers to align package sizes with common dosage amounts while not requiring mandatory reductions.

IMPROVE ACCESS

Hospitals and the patients they serve need access to more affordable drugs. Policies in this category would immediately increase hospital and patient access to less costly, safe drugs.

- **Allow providers and patients to reimport drugs.** It is illegal for individuals or providers to purchase prescription drugs in other countries and bring them back into the U.S. for use. This prohibition includes drugs that were manufactured in the U.S. and sent to other countries for sale and distribution. Reimportation is enticing given the substantial price discounts that are available to purchasers in other countries. While the federal government has opted not to enforce this law against individuals who reimport U.S.-manufactured drugs for personal use, the practice remains illegal. It also is not available to hospitals or other providers who could benefit from access to substantially lower cost drugs. The federal government could loosen restrictions around reimportation to allow individuals, hospitals and other providers to purchase drugs in other countries that were either: a) manufactured in the U.S., or b) manufactured in another country that meets or exceeds U.S. safety standards for drug manufacturing. Under this proposal, FDA would conduct an assessment of the manufacturing standards in other countries and identify those that meet U.S. standards. In addition, FDA would require that any drugs that are imported follow safe transport guidelines.
- **Require mandatory, inflation-based rebates for Medicare drugs.** The Medicaid program consistently achieves better pricing on drugs than the Medicare program. For example, in 2012, the Department of Health and Human Services Office of Inspector General (OIG) found that Medicaid programs achieved rebates worth 47 percent of Medicaid expenditures, while Medicare Part D plan sponsors achieved rebates worth only 15 percent of their expenditures. Medicaid programs also were able to negotiate net unit costs of less than half of the amount paid by Part D sponsors for 110 of the 200 drugs evaluated by OIG. Part D sponsors were only successful in negotiating lower net unit prices for five of the drugs.⁸ Other evidence suggests consistent findings for other drugs purchased for Medicare beneficiaries through Part B of the program. In a 2013 report, OIG found that Medicare could have saved \$2.4 billion (or 26 percent) in Part B spending in 2010 if drug manufacturers had provided Medicare with the same rebates they give to Medicaid programs for just 20 high-cost drugs.⁹

The primary driver behind the lower net unit costs were mandated, additional rebates that

⁸ HHS Office of Inspector General, "[Medicaid Rebates for Brand-name Drugs Exceeded Part D Rebates by a Substantial Margin](#)," April 2015.

⁹ Office of Inspector General, "[Medicare Could Collect Billions if Pharmaceutical Manufacturers Were Required to Pay Rebates for Part B Drugs](#)," September 2013.

kick in when the average manufacturer price (AMP) for a drug increases faster than inflation. This proposal would implement a similar inflation cap on the price of drugs under the Medicare program. Under Medicare Part B, such a cap could be operationalized through a manufacturer rebate to Medicare when the average sales price (ASP) for a drug increases faster than a specified inflation benchmark. A similar cap could be placed on increases in the prices of Part D drugs. This policy proposal would protect the program and beneficiaries from dramatic increases in the Medicare payment rate for drugs, such as increases in the range of 533 percent (Miacalcin, used for treating bone disease), 638 percent (Neostigmine, used in anesthesia) and 1,261 percent (Vasopressin, used to treat diabetes and bleeding in a critical care environment). Such a policy also could potentially generate savings for drugs with price growth above the inflation benchmark.

ALIGN INCENTIVES

Incentives within the health care system do not always direct patients, payers, drug manufacturers or providers to the highest-quality, lowest-cost drug alternatives. These policy proposals would help align incentives toward high value.

- **Implement stricter requirements on direct-to-consumer (DTC) advertising disclosures.** The U.S. is only one of two countries that allows DTC advertising. Physicians routinely report that they receive pressure from patients to prescribe specific drugs based on advertisements. DTC advertising costs drug manufacturers billions of dollars each year and, thus, directly contributes to the price of a drug. Such advertising also drives up health care spending by increasing patient demand for newer, more expensive drugs, even when earlier versions or generics may work just as well.

In 1999, rules governing how much information must be included in DTC advertising were loosened. Since then, there has been an explosion of new ads directed at consumers. While some helpful information is provided to consumers on the drug's use and potential side effects, little to no information is provided on how the drug compares clinically and from a cost perspective to other alternatives. Pricing information also is not required. This policy proposal would direct FDA to implement stricter rules around DTC advertising, specifically requiring additional critical information – such as drug list price for a common course of treatment (or annually in the case of drugs that manage ongoing, chronic conditions) and comparative effectiveness results – to consumers.

- **Remove tax incentives for drug promotion activities.** Drug manufacturers can write off billions of dollars that they spend promoting their products. This not only gives these multi-billion dollar organizations a tax break, it encourages them to promote drugs directly to consumers and prescribers. Information included in these promotions is often incomplete, fails to disclose how the product compares to other treatments in its class and the anticipated cost of a course of treatment, and is linked to increased demand for higher cost drugs. This proposal would remove the tax breaks for drug promotion activities.

- **Develop prescriber education and clinical decision support tools, including prescriber monitoring programs.** This proposal would direct CMS to work with providers to develop clinical decision support and benchmarking tools for drug prescribing practices. Clinical decision support tools could provide prescribers with evidence-based and timely information to help them select the most clinically effective drugs for their patients and promote safe prescribing. Benchmarking tools enable providers to compare their performance with their peers at the local, state and national levels. Similar tools already in use in some hospitals and health systems have been effective in changing clinicians' practice patterns to better align with evidence-based developments and best practices.
- **Test changes to the federally-funded Part D reinsurance program.** Under the Part D prescription drug program, the federal government covers 80 percent of the costs for enrollees who cross the out-of-pocket threshold. Insurers and beneficiaries share the responsibility for the remaining 20 percent, at 15 and 5 percent, respectively. These reinsurance payments are substantial: in 2013, the federal government's portion totaled nearly \$20 billion for approximately 2 million Medicare beneficiaries.¹⁰ This program shields Part D plan sponsors from high costs and may create disincentives for plan sponsors to aggressively negotiate drug prices with manufacturers and manage enrollees' care. This proposal would require that CMS design a pilot project to test a new Part D payment model that either reduces or eliminates reinsurance payments while making appropriate adjustments to the direct subsidy rate. CMS could test whether shifting more of the financial risk to insurers leads to appropriate reductions in program spending due to stronger negotiations with drug manufacturers or improved care management. This alternative is consistent with the Medicare Payment Advisory Commission's recent recommendation on improvements to the Part D program.
- **Vary patient cost-sharing for certain drugs based on value.** Cost-sharing can be a strong incentive for patients and their providers to select the most clinically and cost-effective drug regimen available ("high value" drug). Lower cost-sharing also supports greater compliance with treatment plans and, therefore, could help decrease unnecessary utilization across the health care system, such as unplanned emergency department visits and hospitalizations. This policy would decrease or eliminate cost-sharing to improve beneficiaries' access and appropriate use of high-value drugs.

¹⁰ MedPAC, "[Chapter 6: Sharing risk in Medicare Part D](#)," June 2015.