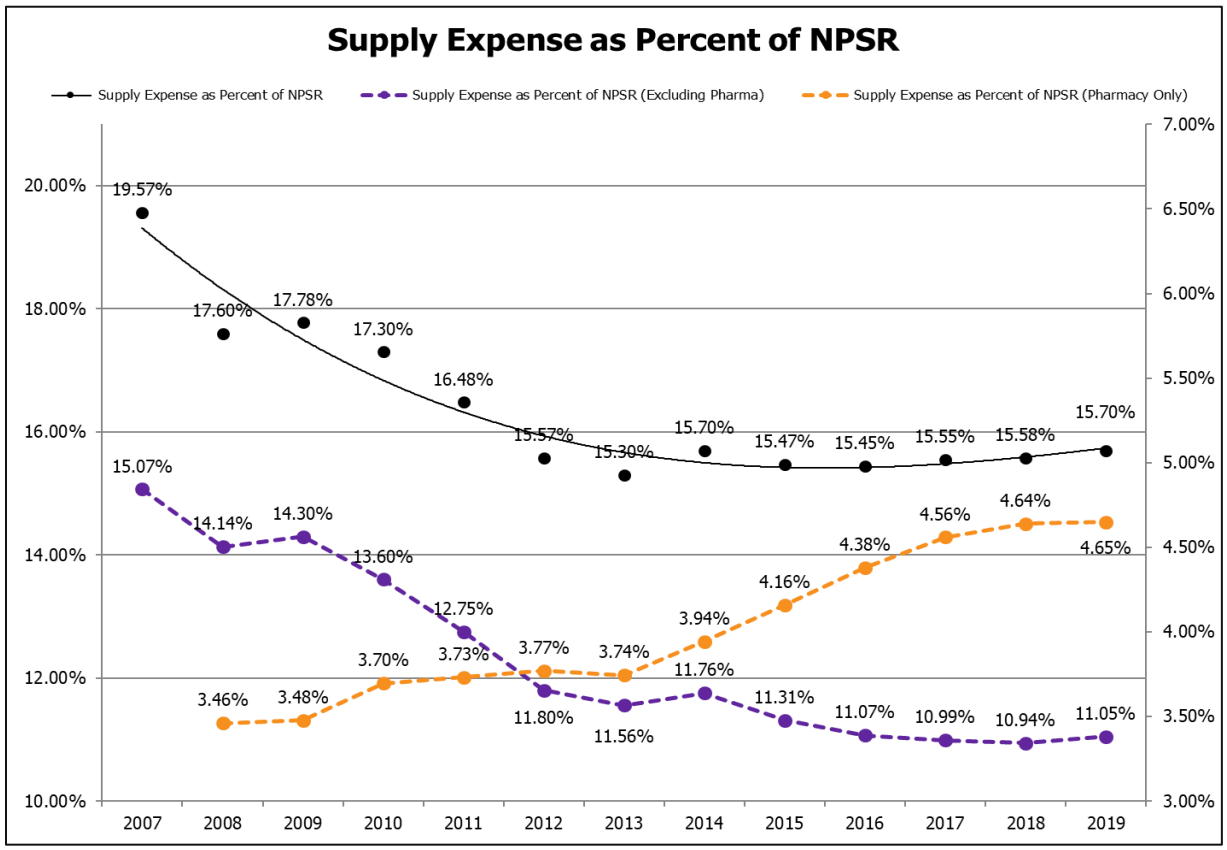
Ascension

Subcommittee on Health Hearing: Follow Up Questions

The Honorable Joe Kennedy

Q1: You noted that Ascension experiences up to 40 new prices increased each week. What types of resources does Ascension have to use just to manage these price increases and how does this impact hospitals?

As mentioned in the testimony, managing the cost of our supply chain is critical for us to carry out our mission. For Ascension, drug costs are the fastest growing part of our supply chain and represent $1.2 billion in annual costs to our system – which continue to grow each year. At the time of the testimony, Ascension had to mitigate against a cumulative 34% increase in drug costs, totaling $564 million – and that's after 340B discount. Since the testimony, we have been able to update our inflation data to incorporate the most recent fiscal year. Based on the updated data, pharmaceutical inflation has attributed greater than $876M (40% cumulative increase) in additional costs over the last five years. To demonstrate the impact pharmacy has on a hospital supply chain, the below graph highlights how drug supply expense as a percent of NPSR has continued to increase as the non-drug supply expense percent has decreased.



As a large health system, a common misconception is that we are able to leverage our size to get significant discounts on drugs. While this is typically the case with the non-pharma supplies, pharmacy manufacturers are only willing to negotiate the price for about 50% of the drugs we buy. We have no leverage as these drugs are patent protected brand drugs or sole-source generics that create a lack of competition between manufacturers. They know this, and 80% of the manufacturers that we have contracts with do not lock in firm pricing for a full year.

In order to monitor and mitigate drug pricing increases, we must increase administrative time and cost to continuously monitor drug pricing and explore low cost alternative therapies that we can implement without compromising patient care. If an alternative therapy is not possible, we are forced to absorb the higher cost of the drug. If we are able to identify a clinically appropriate alternative, it is a long and involved process that takes months to implement. This process involves clinical evaluations, physician buy-in, contracting for alternative, caregiver education, drug stocking, and updating of electronic medical records. During that time, we continue to absorb the higher price.

Q2: Can you share more about how drug shortages have impacted your patients and hospitals? Do drug shortages increase costs for hospitals?

Drug spend represents the fastest growing part of our supply chain and is utilized by nearly every patient during their visit or upon discharge. Therefore, one of pharmacy's primary goals as a health system is to ensure that hospitals have access to medications to ensure we get patients the right medications, at the right times. These drug shortages lead to an increase in hospital drug and administrative spend. More specifically, the drug shortages can lead to:

- Increased spend for medications due to switching to more expensive alternatives and purchasing off contract or through alternative channels
- Increased time and costs focused on the administrative tasks needed to identify and implement safe alternative therapies
- Increased risk for medication errors

Currently, Ascension is experiencing shortages on 187 medications, with 14 of those being deemed critical (18% of Ascension's critical drugs on shortage). This disruption in supply requires constant review and analysis, communication to the hospitals, exploration of clinically equivalent therapies, negotiation of new contracts when possible, and implementation of the new drug across the system. For Ascension, this requires a dedicated team that spends over 40 hours per week completing administrative tasks. In addition to the administrative costs, drug prices will typically increase as manufactures impose price increases for shortages where they may be the only alternative.

Q3 How much can patient out-of-pocket expenses change as a result of increased drug prices?

For hospitals, inpatient stays are generally reimbursed through fixed bundled payments that are set by payors in advance to cover the total cost of an admission. Generally, these bundled payment amounts are not adjusted during the year when costs go up. When drug costs go up, the bundle does not so as a health system we must make adjustments elsewhere to mitigate the rising costs and continue to deliver high quality care. Eventually, these increased costs affect consumers when they result in high premiums to cover the increased cost.

However, as patients transfer from the inpatient to the retail prescription setting, they begin to share in the rising drug costs. The continued new entrants of expensive medication therapies like specialty pharmacy (anticipated to account for 50% of the total drug spend by 2020) accelerates the growth in the prescription drug sector which is quickly becoming one of the fastest growing health categories. As the prescription drug economics continue to rise, insurers, government, and other payers will find it difficult to manage costs and it will result in increased cost sharing, increased member contributions to premiums, and potential elimination of health plans. In addition to the increasing spend on prescription drugs, patient outcomes will be impacted as their rising benefit cost will lead to reduced adherence as some will be unable to afford their chronic medications. This will put the patient at risk and could potentially lead to increased admissions to hospitals, resulting in a higher overall cost of care.

Q4: As a percentage, how large are the drug increases you have experienced in the past several years?

As highlighted in questions one, drug costs are the fastest growing part of our supply chain and represent $1.2 billion in annual costs to our system – which continue to grow each year. At the time of the testimony, Ascension had to mitigate against a cumulative 34% increase in drug costs, totaling $564 million – and that's after 340B discount. Since the testimony, we have been able to update our inflation data to incorporate the most recent fiscal year. Based on the updated data, pharmaceutical inflation has attributed greater than $876M (40% cumulative increase) in additional costs over the last five years. The following information highlights the year-over-year inflation percentage since 2015:

- FY15 = 11.2%
- FY16 = 9.8%
- FY17 = 6.3%
- FY18 = 6.8%
- FY19 = 4.5%

The Honorable Michael C. Burgess, M.D.

Q5: Something I find particularly concerning about our drug supply chain is the possibility of drug shortages. These can occur because of natural disasters, manufacturing issues, or business decisions. What are each of your respective companies doing to prevent drug shortages?

As a health system, one of our primary goals is to ensure that we have access to medications to ensure we get our patients the right medications, at the right times. Currently, Ascension is experiencing shortages on 187 medications, with 14 of those being deemed critical (18% of Ascension critical drugs on shortage). These drug shortages lead to an increase in administrative burden and hospital spend. More specifically, the drug shortages lead to:

- Increased spend for medications due to switching to more expensive alternatives and purchasing off contract or through alternative channels
- Increased time and costs focused on the administrative tasks needed to identify and implement safe alternative therapies
- Increased risk for medication errors

Currently, we are working with our distributors and contracted suppliers, as well as developing tools internally to help mitigate the risk of drug shortages. The Ascension contracting team works with our contracted distributors and suppliers to create a secured allocation program for select shortage products, whereby we work with suppliers to provide a dedicated allocation of critical products for our participants in times of shortage. Additionally, we are in the process of building a historical trend database that will allow us to predict when shortages will occur. Until this can be built, we have two full-time positions and data action analysts dedicated to managing shortages and backorders.

The Honorable John Shimkus

Q6: Given that most of the witnesses on the panel have referenced the role of creating value in the health care supply chain, please comment on: Existing areas where Congress or the Administration may have needlessly added to the cost that patients or the government pays for a particular product, service, or

intervention. For example, do you have recommendations on how reforms to existing laws like Stark and the Anti-Kickback Statute could accelerate value-based contracting within Medicare and Medicare Advantage?

The current regulatory framework created by the federal government for healthcare providers is overly complex, duplicative, and extremely burdensome. Hospitals, physicians, post-acute care providers, and other healthcare practitioners must dedicate far too much of their time to satisfying administrative regulatory requirements rather than caring for patients. We greatly appreciate and support the work that CMS has undertaken to reduce this regulatory burden through their Patients Over Paperwork Initiate.

Despite some progress that has been made, more works needs to be done. The American Hospital Association released a report that found hospitals must comply with more than 620 discrete regulatory requirements, costing hospitals, health systems, and post-acute care providers nearly $40 billion each year across the industry.[1] Notably, while the delivery of healthcare has modernized, HHS, CMS, and other agencies of the federal government continue to view and regulate healthcare as a volume-based system rather than a value-based delivery system where providers are increasingly taking risk for the care they furnish to their patients.

We believe Congress and the Administration can take a number of concrete steps to help reduce the burden on healthcare providers. Though not an exhaustive list, we strongly support the following regulatory reforms:

- **Promote delivery system transformation through**:
  - Expanded waivers of certain Medicare fee-for-service (FFS) regulations that hinder the broad implementation of delivery system reform models;
  - Center for Medicare and Medicaid Innovation (CMMI) reforms that would improve the uptake of transformational models of care; and
  - Modernization of fraud and abuse regulations—in coordination with the HHS Office of Inspector General (OIG), as appropriate—to promote the shift towards value-based, patient-centric care.

- **Reduce administrative burdens, redundancy, and unnecessary costs by**:
  - Removing redundancies and inaccuracies inherent to Medicare quality reporting programs by harmonizing program requirements and risk adjusting readmission and other outcome measures to account for sociodemographic factors. CMS should also continue the suspension of hospital star ratings from the *Hospital Compare* website until methodological flaws are fully addressed and suspend post-acute care quality reporting requirements associated with the IMPACT Act pending further provider engagement;
  - Providing regulatory relief under Medicare and Medicaid reimbursement systems, including through: reversal of the recent Medicare payment reduction and reporting mechanisms applicable to 340B drugs and program participants in favor of addressing the root causes of increasingly high drug prices; permanent non-enforcement of certain direct supervision requirements; permanent non-enforcement of the "96-hour rule" for critical access hospitals; adjustments to co-location requirements; increased flexibility around how hospitals advise patients on post-acute provider options; formal termination of the Pre-Claim Review Demonstration for home health agencies; increased coverage and payment for telehealth services in Medicare; and use of the original timeline for phasing-out Medicaid provider pass-through payments; and
  - Streamlining and simplifying Medicare health information technology requirements.

[1] Available at: http://www.aha.org/content/17/regulatory-overload-report.pdf

Regarding reforms to the Stark Law and the Anti-Kickback Statute, we have attached our White Paper entitled Legal Barriers: Inhibiting the Transition to Value-Based Care, which provides an in-depth examination of these issues. In summary, we believe strongly that our laws and regulations should support and protect clinical integration arrangements, as they can lead to better care and lower costs. While having appropriate protections against fraud and abuse, healthcare law and policy should encourage integration among hospitals, physicians, and other providers that establish incentive payments or shared savings programs to: (1) promote accountability for quality, cost, and overall care for patients; (2) manage and coordinate care for patients; or (3) encourage investment in infrastructure and redesigned care processes for high-quality and efficient care delivery for patients.

Q7: How do we ensure that these value-based reforms benefit patients and protect taxpayers?

Ascension is committed to a long-term vision of a sustainable, high-quality health system that serves individuals as whole persons throughout the course of their lifetime. As part of this, we strongly support the movement towards value-based care arrangements. It is crucial that, as we move forward with healthcare transformation, we do so with the patient's needs at the forefront. It is also vitally important that we address the rising cost of health care by moving away from fee-for-service models that reward volume of care to value-based models that support improving quality and reducing costs.

It is important that we continue to test new alternative payment models as we work toward finding the best methodologies for improving care that benefits patients while addressing rising costs by improving care coordinate and preventing more costly outcomes that result in increased use of the emergency department and the inpatient setting. While these models are being tested and evaluated, some delivery models are showing clear benefits. These include improving chronic disease management, better coordination of primary care services and the use of technology including improved information systems, remote patient monitoring, and telehealth services, which when managed appropriately can often facilitate early intervention in an exacerbation of a chronic disease that can prevent a costly inpatient stay and improve the quality of life for the patient.

It is also important that we manage prescription drug therapies carefully and appropriately. There is strong evidence that the delivery of medication therapy management by pharmacists is effective at improving care and lowering overall costs. Medication therapy management (MTM) is care provided by pharmacists with the goal of ensuring the most effective use of drug therapy and consists of five core elements designed to ensure the best therapeutic outcomes for patients. The five core elements include medication therapy review, a personal medication record, a medication-related action plan, intervention or referral and documentation and follow up. Studies have indicated that MTM can produce healthcare cost savings and a positive ROI for health systems.[2] Adherence to medication therapy is an important to ensure positive patient outcomes as well as lowering the overall cost of healthcare. Nationally, nonadherence costs the healthcare system an estimated $100 to $289 billion annually. Not only does nonadherence increase costs, but it also leads to poorer health outcomes for patients.[3] Pharmacist led MTM can directly impact these outcomes positively and reduce overall healthcare costs.

To facilitate the move toward value-based care arrangements, the federal fraud and abuse laws need to be modernized. These laws were written to protect against overutilization in FFS payment models where self-referrals and inducements can lead to higher payments from Medicare. Such protections make sense in FFS payment models. But the financial risk inherent to value-based payment models provides far stronger guardrails against overutilization and fraudulent practices. And appropriate use of quality performance metrics ensures

[2] https://www.cdc.gov/dhdsp/pubs/guides/best-practices/pharmacist-mtm.htm

[3] https://www.pharmacist.com/medication-adherence

protection against stinting and sub-standard care. Where fraud and abuse laws are a safeguard against practices that drive up costs *in a FFS system*, alternative payment models often create payment limits and quality thresholds for an entire episode of care, placing providers at risk for both costs and outcomes. In these models, if costs go up or quality goes down, participating providers may incur direct financial losses – or worse. These kinds of enforcement mechanisms provide stronger and more effective guardrails against increases in the volume and costs of services, or the decline in quality of care, than the fraud and abuse laws ever placed on the FFS system.