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Prescription Drug Pricing in the United States: Current Issues and Prospects for Modifications and Reform

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I. Introduction

a. Unlike many countries in the world, the United States government does not regulate drug prices. Control of drug prices occurs through the private marketplace when insurers – often through their contracted pharmacy benefit managers (PBMs) – negotiate rebates and formulary benefit design.

b. That said, the federal government does exercise significant leverage in drug pricing decisions through the Medicare Part D program, for drugs covered under Medicare Part B, and through the Medicaid prescription drug rebate program. To a lesser degree, the federal government does have some leverage in the individual insurance market, as modified by the Affordable Care Act.

c. In addition, states are able to exercise control over drug pricing through supplemental rebates in the Medicaid program.

d. Even before his election, and in the months since taking office, President Trump has not been shy about expressing his views over prescription drug pricing and has strongly hinted that the federal government should play more of a role in regulating drug pricing.

e. This paper will address:

i. Federal government regulation and oversight of drug pricing

ii. The role of pharmacy benefit managers (PBMs)

iii. Public policy options to be aware of in the year ahead

II. Federal government regulation and oversight of drug pricing

a. The Medicare program

i. There are two pathways to coverage of prescription drugs under the Medicare program: Medicare Part B and Medicare Part D.

ii. Part B drugs

1. Background

a. Historically, the Medicare program did not cover most outpatient prescription drugs. Limited coverage was available as a medical benefit for some classes of drugs.

b. Drugs are covered under Part B if they are:

i. Administered incident to a physician's service and not usually self-administered. Social Security Act § 1861(s)(2)(S).
    1. "Usually" is defined in the Medicare benefit policy manual as, with respect to Medicare beneficiaries, more than 50% of the time. Medicare Benefit Policy Manual Ch. 15 § 50.2.C.
    2. Some common examples of these "incident to" drugs are chemotherapy drugs and drugs used to treat rheumatoid arthritis.

ii. Specifically named in the statute. Social Security Act § 1861(s)(2)(I), (J), (O), (Q), (T).
    1. Erythropoiesis stimulating agents
    2. Anti-organ rejection agents
    3. Oral anti-cancer agents
    4. Oral anti-emetic agents

iii. Necessary for the effective use of durable medical equipment. Medicare Benefit Policy Manual Ch. 15 § 110.3.
    1. E.g., nebulizers used for administration of albuterol.

2. Coverage
    a. Although this authority is not commonly exercised for Part B drugs, CMS does have the authority to limit coverage for Part B drugs through its "reasonable and necessary" authority.
        i. Medicare cannot pay for items and services that are not "reasonable and necessary for the diagnosis or treatment of illness or injury." Social Security Act § 1862(a)(1)(A).
    b. CMS has, in the past, issued coverage decisions limiting coverage for some part D drugs:
        i. PET scans and PET imaging agents
        ii. Provenge®
    c. CMS contractors can also issue local coverage determinations that a drug is usually self-administered and therefore not covered under Part B.
3. Payment for Part B drugs
    a. CMS reimburses the entity that bills Medicare for a part B drug (e.g., physician, hospital, pharmacy) at the average sales price (ASP) of the drug plus 6%. Social Security Act § 1847A.

i. The 6% add-on is reduced as a result of the sequestration order signed by President Obama on March 1, 2013 for claims with dates of service on or after April 1, 2013. As a result, the ASP add-on, for as long as sequestration is in effect (at least through 2025) is only 4.8%.

b. ASP is defined as the total of all of the manufacturer's sales to all purchasers in the United States divided by the total number of units sold. Social Security Act § 1847A(c)(1).

i. Some sales are exempt from ASP calculation:

1. Sales exempt from Medicaid best price
2. Sales at a nominal charge.

ii. ASP is determined net of discounts, rebates, chargebacks, and other price concessions. Social Security Act § 1847A(c)(3).

1. This is a major change from the policy in effect prior to 2003, which did not take price concessions into effect when determining the Medicare payment amount for Part B drugs. The failure to account for price concessions led to multiple

determinations by agencies such as the HHS Inspector General, the Congressional Budget Office and the Office of Management and Budget that Medicare was dramatically overpaying for Part B drugs.

iii. The statute contains special rules where ASP is not available for a new drug.

iv. ASP determinations are made on a quarterly basis.

c. Manufacturers are required to report ASP to CMS on a quarterly basis. By statute, these reports are highly confidential and generally cannot be disclosed by CMS.

d. The HHS Inspector General is authorized to monitor the market price of Part B drugs ("widely available market price"). If the Inspector General determines that the ASP exceeds the market price by a specified percentage, CMS can disregard ASP and must substitute payment at the widely available market price for the drug in the succeeding quarter. Social Security Act § 1847A(d)(3)(C).

e. On balance, the ASP+6 mechanism for reimbursing for Part B drugs reflects an attempt by Congress and CMS to recognize the market forces that occur in the sale of Part B

drugs. These market forces had been ignored under the prior reimbursement model.

i. However, the ASP+6 methodology remains subject to criticism. The 6% add-on is criticized for driving up the cost of these drugs because the higher the base rate for the drug, the higher the 6% add-on and therefore the greater incentive to prescribe a more expensive drug.

iii. Medicare Part D

1. In December, 2003, President George W. Bush signed the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) into law. Pub. L. No. 108-173, 117 Stat. 2066 *et. seq.* (Dec. 8, 2003). Title I of the MMA created an outpatient prescription drug benefit in the Medicare program. Social Security Act § 1860D-1 – D-43.

a. Unlike Part B drugs, the Part D benefit can be thought of as a pharmacy benefit; the program covers drugs that are commonly dispensed via pharmacies or mail order.

b. In addition, unlike traditional Medicare benefits, Part D is only available through private insurance plans. If a Medicare beneficiary wants coverage for Part D covered

drugs, they must enroll through a private Part D plan or a Medicare Advantage plan.

2. Definition of a Part D covered drug
    a. The statute contains a three-part definition of a Part D drug; CMS regulations contain a four-part test.
    b. The statutory definition: A drug is covered under Part D if it is:
        i. Approved by the FDA.
        ii. Can only be dispensed pursuant to a prescription.
        iii. Not otherwise covered under Medicare Part B. Social Security Act § 1860D-2(e)(1), (2)(B).
    c. The CMS definition
        i. CMS adds to the statutory definition a requirement that the drug be dispensed for a medically accepted indication. 42 C.F.R. § 423.100. The courts have considered whether this definition is supported by the statute. *See Layzer v. Leavitt*, 770 F. Supp. 2d. 579 (S.D.N.Y. 2011). *But see Kilmer v. Leavitt*, 609 F. Supp. 2d. 750 (S.D. Ohio 2009).
3. Coverage of Part D covered drugs
    a. Unlike Part B drugs, which are essentially guaranteed of coverage once they are approved by the FDA (unless, in a

rare case, CMS or its contractors issue a restrictive national coverage determination), there is no guarantee that a Part D plan will cover a particular drug except in very limited circumstances.

b. CMS regulations only require that a Part D plan cover two drugs in every category or class of drugs that are not therapeutically equivalent or bioequivalent (unless, of course, the category or class only contains one drug). 42 C.F.R. § 423.120(b)(2)(i).
    i. Thus, Part D plans are free to exclude drugs from a formulary, or else require an exceptions process for a beneficiary to obtain access to a drug.

c. However, in the case of six particular categories or classes of drugs, CMS requires Part D plans to include all drugs in the category or class. Medicare Prescription Drug Manual Ch. 6 § 30.2.5. These classes are:
    i. Anti-depressants
    ii. Anti-psychotics
    iii. Anti-organ rejection
    iv. Anti retrovirals
    v. Anti-cancer agents

vi. Anti-convulsants. *See also* Social Security Act § 1860D-4(b)(3)(G) and 42 C.F.R. § 423.120(b)(2)(v), (vi).

d. The statute expressly prohibits CMS from establishing a formulary. Social Security Act § 1860D-11(i).

e. As a condition of having their drugs covered under Part D, manufacturers must grant a 50% discount off of the negotiated price of a drug for beneficiaries who are in the Part D coverage gap ("donut hole"). Social Security Act §§ 1860D-14A; 1860D-43.

4. Payment for Part D covered drugs

a. Because Part D drugs are only available through private plans, those plans are responsible for:

i. Benefit and formulary design;

ii. Negotiations on purchase price with manufacturers;

iii. Negotiations on reimbursement rates with pharmacies;

iv. Rebates and price concessions.

b. Most Part D plans rely on PBMs for these negotiations.

c. Moreover, the government is prohibited from interfering in these negotiations. Social Security Act § 1860D-11(i).

b. The Medicaid program

i. Outpatient prescription drugs are an optional benefit under the Medicaid program. Social Security Act § 1905(a)(12). However, all state Medicaid plans cover prescription drugs to some degree.

ii. Options available to states to control outpatient prescription drug spending.

1. States are permitted to utilize some prescription drug management tools to control drug spending.

2. For example, states may:

a. Subject a drug to prior authorization. Social Security Act § 1927(d)(1).

i. If a drug is subject to prior authorization, the state must provide a response within 24 hours and provide for the dispensing of at least a 72-hour supply if the drug in an emergency situation. Social Security Act § 1927(d)(5).

b. Exclude some drugs from coverage entirely.

i. Drugs used to treat anorexia, weight gain or loss.

ii. Fertility agents

iii. Cosmetic purposes

iv. Cough suppressants

v. Prescription vitamins and mineral products

vi. Entire list at § 1927(d)(2)

c. States may impose a formulary.

i. However, formulary management techniques in Medicaid are not similar to formulary management techniques used in private insurance or in Medicare Part D. There are five main requirements of formularies in Medicaid:

1. Formulary must be approved by a committee consisting of individuals with medical training, experience and expertise.
2. Generally, the formulary must include any drug from a manufacturer that has agreed to pay rebates (see b.iii. below).
3. Drugs can be excluded from a formulary only if the drug does not have a "significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome." Social Security Act § 1927(d)(4)(C).
4. If a drug is excluded from a state's formulary, it must be made available through a prior authorization process.

5. Other requirements that the Secretary may impose in order to achieve program savings (consistent with beneficiary health).

ii. Thus, unlike in Part D or the private insurance marketplace, where a formulary may only cover two or three drugs in a category or class, states generally have very limited flexibility to exclude a drug from formulary.

d. States can impose limits on the quantity of a drug dispensed or the number of refills.

iii. Requirements of manufacturers

1. The Medicaid prescription drug statute reflects a compromise between CMS, states and manufacturers (the so-called "Grand Bargain"). In exchange for generally favorable coverage of drugs, manufacturers are required to pay rebates and agree to other requirements as a condition of having their drugs covered.

2. Rebate requirements

a. As a condition of having its drugs covered under Medicaid, a manufacturer must:

i. Participate in the 340B program ((b), below)

ii. Agree to grant FSS pricing ((c), below)

iii. Pay rebates that are split between the states and federal government ((d), below)

b. 340B program

i. The 340B program requires that drug manufacturers sell their products to certain "covered entities" at the Medicaid price. 42 U.S.C. § 256b.

ii. Covered entities are generally those entities/health care providers that serve low-income populations. There are a total of 15 types of covered entities, including:

1. Community health centers
2. Heavily disproportionate share hospitals
3. Other hospitals such as cancer hospitals and pediatric hospitals
4. AIDS Drug Assistance Programs
5. Family planning clinics

iii. The 340B program is operated by the Health Resources and Services Agency (HRSA) and is subject to multiple criticisms:

1. No clear definition of who constitutes a "patient" of a covered entity

2. The ability of covered entities to bill private insurance, Medicare and Medicaid at a much higher rate than the acquisition cost
3. Uneven and biased enforcement by HRSA against manufacturers and in favor of covered entities
4. Program operated without clear regulatory oversight

iv. Two significant forms of guidance expected this year:

1. Civil monetary penalty rule (82 Fed. Reg. 1210 (Jan. 5, 2017)). The rule has been delayed at least until October 1, 2017.
2. "Mega-Guidance" (80 Fed. Reg. 52300 (Aug. 28, 2015)). This guidance has not been finalized.

c. Federal Supply Schedule (FSS)

i. Entities that contract with certain branches of the federal government are required, as a condition of contracting, to grant "most favored nation" pricing to government entities.

ii. For purposes of contracting with the federal government, pharmaceutical manufacturers must grant significant discounts to:

1. The Department of Defense (TriCARE)
2. The Department of Veterans Affairs
3. Public Health Service entities (including the Indian Health Service, federal Bureau of Prisons, etc.)
4. Coast Guard

iii. Prices to these entities are, on average, between 41% and 50% of the average wholesale price of the drug. Congressional Budget Office, "Prices for Brand-Name Drugs Under Selected Federal Programs" at 8 – 9 (June, 2005).

d. Medicaid Rebates

i. Manufacturers must sign a prescription drug rebate agreement with the Secretary of HHS under which they must agree to provide rebates to have their drugs covered under Medicaid. Social Security Act § 1927(b).

ii. Rebates are equal to the greater of (for brand-name drugs) 23.1% of the average manufacturers

price (AMP) of the drug or AMP minus best price. Social Security Act § 1927(c)(1)(A)(ii).

1. "Best price" generally equals the lowest price available from the manufacturer to a purchaser, subject to several exceptions (such as 340B pricing, FSS pricing, and sales to Medicare Part D plans). Social Security Act § 1927(c)(1)(C)(i).

iii. Manufacturers must also pay an additional, inflation-related rebate if the price of their product increases by greater than the consumer price index. Social Security Act § 1927(c)(2)(A)(ii)(II).

iv. Generally, if a manufacturer agrees to pay rebates, coverage of its drugs are guaranteed under the Medicaid program. This limits the flexibility of states to manage their prescription drug spend and is a potential subject for legislation or CMS waivers in 2017.

III. The role of pharmacy benefit managers (PBMs)

a. PBMs play a key role in the management of prescription drug benefits in private and public health insurance plans in the United States.

i. PBMs administer prescription drug plans for more than 266 million Americans who have health insurance from multiple plan sponsors, including commercial health insurance plans, self-insured employer plans, union plans, Medicare Part D plans, the Federal Employee Health Benefits Program, state government employee insurance plans, Medicaid managed care plans, and many other insurance plans.

ii. According to the Pharmaceutical Care Management Association (PCMA, the trade association representing most PBMs in the United States), PBMs are projected to save prescription drug plan sponsors $654 billion in prescription drug costs in the United States over the next decade. https://www.pcmanet.org/our-industry/.

b. PBMs are subject to multiple layers of regulation by widely varying government entities:

i. ERISA; Department of Labor

ii. Medicare Part D and Medicare Advantage

iii. Center for Consumer Information Insurance Oversight (CCIIO)

iv. HHS Office of Civil Rights

v. Medicaid managed care

vi. State regulation of the individual insurance market

vii. State regulation of pharmacies

c. PBMs fulfill their obligations to prescription drug plan sponsors in several ways:

i. PBMs manage formulary and benefit design for prescription drug plan sponsors.

ii. PBMs work with plan sponsors to increase generic dispensing rates and establish price points for generic medications as a means of driving efficiencies.

iii. PBMs negotiate with prescription drug manufacturers to obtain rebates and price concessions that are largely passed on to plan sponsors and to plan enrollees at the point of sale.

iv. PBMs negotiate with pharmacies in order to assist plan sponsors in developing a robust pharmacy network with quality and other value-based parameters.

v. PBMs encourage plan sponsors to utilize mail order and specialty pharmacies.

vi. PBMs manage the exceptions and appeals processes for prescription drug plan sponsors.

IV. Public Policy Options in 2017

a. Given President Trump's frequent references to concerns over prescription drug pricing, and the interests of many members of Congress to address a high-profile public policy issue, it is likely that there will be legislative and regulatory proposals to address prescription drug pricing in 2017. Below, we list several proposals that are likely to be advanced, along with our assessment of the likelihood of their adoption.

b. Regulation of drug prices in the group health plan market
    i. It seems inconceivable to us that Congress will attempt to regulate prescription drug prices in the group health plan market.
    ii. PBMs play a significant role in driving price concessions in the group health plan market. Congress is likely to let that role continue without intervention.
c. Regulation of drug prices in the individual insurance market
    i. Little likelihood of legislation on the federal level in this area. Traditionally, states have regulated the individual insurance market.
        1. Of course, this changed to some degree with the enactment of the Affordable Care Act.
    ii. Many states are considering legislation to address issues with prescription drug pricing in this year's legislative session. States have, for the past two decades, attempted to assert greater regulatory authority into prescription drug manufacturer regulation.
        1. 2000 – 2010 gift ban legislation.
            a. Meals, gifts, non-professional travel banned
            b. Some states required disclosure of any in-kind or monetary payment to physicians.
        2. Federal legislation (Physician sunshine law) enacted as part of ACA seems to have halted state action for now.

iii. The launch of Sovaldi® in December, 2013 at $80,000 list price highlighted this issue again.

1. These drugs exposed both manufacturers and insurers to criticism:
    a. Manufacturers for high list price
    b. Insurers for shifting high cost sharing to enrollees (e.g., specialty drug tiers).
2. State legislative attempts included
    a. Limits on specialty tiering
    b. Co-pay caps or limits on cost sharing
    c. Oral parity
    d. Transparency in cost sharing and formulary design
    e. Triggers if annual price increases exceed specified percent (e.g., 10%)

iv. Transparency legislation

1. Required reporting of costs that are presumed to lead to high drug costs:
    a. R&D costs
    b. Clinical trial costs
    c. Administrative costs
    d. Marketing and advertising costs
    e. Acquisition costs

f. Total profit

g. Financial assistance through patient assistance programs

2. In some cases, data protected from public disclosure

3. Some legislative initiatives were also coupled with price caps

a. Unclear how states could enforce these caps due to ERISA, Part D pre-emption

v. Status of legislation

1. By the end of the 2016 legislative sessions, at least 24 bills had been introduced in 13 states:

a. Transparency without price controls: 1 enacted (Vermont) and 6 failed (CA, CO, LA, MN, VA, WA)

b. Transparency legislation with price controls: 6 failed (MA, NJ, NY, PA, RI, TN)

2. 2017 legislative outlook

a. 40 transparency bills filed in at least 22 states

i. These bills are focused less on launch price (Sovaldi® scenario) and more on price gouging (e.g., EpiPen).

b. Value based payment models as an alternative to price controls and transparency?

d. Permitting re-importation of prescription drugs into the United States

i. Section 1121 of the MMA (FFDCA § 804) authorized the Secretary of HHS to issue regulations, in consultation with the US Trade Representative and the Commissioner of Customs, to permit the importation of drugs by a pharmacy or wholesaler into the United States from Canada.

ii. The regulations must:

1. Require that safeguards be in place to ensure that imported drugs are safe and effective;
2. Require that the importer comply with record-keeping requirements;
3. Require additional safeguards to protect public health;
4. Require testing for safety.

iii. The legislation also directed the FDA to focus enforcement away from individuals who purchase drugs from Canada.

iv. However, under the statutory provision, it only becomes effective if the Secretary makes the following certifications to Congress. FFDCA § 804(l)(1).

1. The program poses no additional risk to public health and safety.
2. The program will result in a "significant" reduction in costs of products to American consumers.

v. The Secretary has never made the certification under section 804(l)(1).

e. Require rebates in Medicare Part D

i. The Part D law contained a massive shift in liability for prescription drug costs for dual-eligible enrollees.

1. Prior to the enactment of Part D, prescription drug for dual-eligible enrollees were covered by Medicaid because Medicare lacked a prescription drug benefit.
2. Part D shifted the burden of drug spending for this population to Medicare, alleviating a huge burden for states.

ii. However, states had been able to collect rebates for drugs dispensed to duals. Although the cost of covering these drugs went away, so did rebate dollars.

iii. The Obama Administration included budget proposals to require rebates from manufacturers for drugs dispensed to duals.

iv. Recently, the director of the Office of Management and Budget (OMB) in the Trump Administration has speculated publicly on whether the elimination of rebates for drugs dispensed to duals was good public policy. Carolyn Y. Johnson, "The White House budget director dropped a hint about how Trump could bring drug prices down," The Washington Post (May 12, 2017), available at https://www.washingtonpost.com/news/wonk/wp/2017/05/12/the-white-house-budget-director-dropped-a-hint-about-how-trump-could-bring-drug-prices-down/?utm_term=.c381047a0861.

f. Repeal or waive part D non-interference clause

i. As noted above, Social Security Act section 1860D-11(i) prohibits CMS from interfering in negotiations between Part D plans, pharmacies, and pharmaceutical manufacturers.

ii. In theory, Congress could repeal § 1860D-11(i), or CMS could waive or modify it through the Centers for Medicare and Medicaid Innovation (CMMI).

iii. The chances of either happening are highly unlikely, but not impossible.

g. Implement a new demonstration project altering Part B drug pricing

i. In March, 2016, CMS proposed a two-phase Part B drug payment model through CMMI. 81 Fed. Reg. 13230 (March 11, 2016). The model was designed to be in effect for five years.

ii. Under the first phase of the model, physicians and hospital outpatient departments would no longer receive ASP + 6% for the drug. Rather, they would receive ASP + 2.5% plus a $16.80 per drug administration fee.

1. The flat fee would be increased by the CPI (medical care) each year of the demonstration project.

2. These add-on payments were projected to be budget neutral relative to current law.

3. The theory behind phase one was that the current system penalized physicians for choosing a lower-cost drug.

iii. Under the second phase of the model, CMS would attempt to implement value based payment models by replicating the strategies used by PBMs

to control drug prices, including discounting or eliminating beneficiary cost sharing; evidence-based clinical support tools; indications and effectiveness based pricing; reference pricing; and risk sharing agreements based on outcomes.

iv. Under the model, all providers and suppliers furnishing and billing for Part B drugs would be required to participate in the model, although not in every phase of the model. All Part B drugs and biologicals would be included in the model.

v. CMS received significant push-back from its proposed model. In December, 2016, CMS announced that it would not implement the model. The new Administration, could, of course, implement it.

h. Revisions to Medicaid prescription drug rebate statute

i. State Medicaid directors are increasingly complaining that the existing prescription drug rebate program does not give them significant leverage to control prescription drug costs because states are effectively required to cover all drugs once the manufacturer has agreed to pay rebates. Cathy Kelly, "Medicaid Drug Formulary Ideas Floated, But Manufacturers Are Skeptical," Pink Sheet, March 1, 2017.

ii. Medicaid directors are urging Congress to re-write Social Security Act § 1927 to give them more flexibility in coverage of prescription drugs, in a way that would better replicate Medicare Part D.

iii. CMS could, in theory, adopt such policies through its waiver authority under § 1115 of the Social Security Act, although waiver authority is likely not sufficient to fully resolve Medicaid directors' concerns.

i. Enhance PBM transparency

i. Senator Ron Wyden, the ranking Democrat on the Senate Finance Committee, has introduced the Creating Transparency to Have Drug Rebates Unlocked (C-THRU) Act of 2017.

ii. In addition to requiring reporting additional information regarding rebates and price concessions by PBMs, the legislation would also generally require that Part D plans and plans on the Exchanges submit information regarding rebates and price concessions to HHS, which HHS would make available on its website in aggregated form. The legislation would also require that HHS specify a minimum percentage of price concessions that a PBM would have to pass through to its Part D or Exchange plan requirements. Finally, the legislation would re-define the phrase "negotiated price" in the Part D regulations to reflect a requirement that most price concessions be passed through to consumers at point of sale.

iii. Under Part D regulations, the term "negotiated price" generally means the price that the pharmacy pays for the drug, reflecting all price concessions that can "reasonably be determined at the point of sale." 42 C.F.R. § 423.100. The phrase "negotiated price" is crucially important in

Part D. Many key concepts in the program turn on the negotiated price of a drug:

1. Beneficiary coinsurance, especially when the drug is in a specialty tier.
2. Beneficiary payments during the coverage gap.
3. The pharmacy dispensing fee.
4. Reinsurance.
5. Reporting of direct and indirect reimbursement (DIR) to CMS.

iv. The focus of the Wyden legislation is to require that all rebates be passed through at the point of sale. If price concessions cannot be determined or are unknown at the point of sale, the legislation would require an estimate of the price concessions and passed through to the Part D or Exchange enrollee.

v. In theory, CMS could accomplish much of the focus of the Wyden legislation through regulations or sub-regulatory guidance, by changing the definition of "negotiated price" or by de-defining the phrase "reasonably be determined."

j. Alternative reimbursement models for innovative technologies

i. Another issue in prescription drug pricing involves the use of alternative payment models for new innovative technologies.

ii. The FDA approval of new direct-acting antivirals to treat Hepatitis C introduced a new paradigm in the drug pricing debate: how much would

payers be willing to pay today for a therapy that is a cure for a disease that would otherwise consume massive amounts of medical costs in the future?

iii. This question will gain new urgency when the FDA begins to approve gene therapies that, in theory, will involve the one-time administration of a gene-altering or gene-modifying treatment that will cure a (often) rare disease.

iv. Some questions:

1. Should a payer be forced to bear the price of the new therapy up front when the benefits will accrue, potentially to other payers, over years or decades?
2. Can the payments be amortized over some period of time? If so, how do those payments affect existing payment regimes such as ASP reporting and Medicaid best price?
3. How would social investment models work in this context? If an investor is willing to advance the up-front cost of a therapy and accept repayment over time with a premium for medical savings, how will current payment regimes reflect such a model? For example, would the re-payment to an investor constitute an "expenditure for medical assistance" under the Medicaid program such that the state can be reimbursed for the expenditure?

v. These are issues that are going to need to be addressed rapidly as FDA approval of the first gene therapies are rapidly approaching.

k. Use of current Part D authority regarding high cost drugs

i. CMS has flexibility under its current rules and sub-regulatory guidance to consider a range of changes short of legislation on high cost drugs. Options include:

1. Make it easier for plans/PBMs to make negative midyear formulary changes (such as excluding a drug or implementing utilization management protocols) in certain situations (e.g., market events such as availability of new brand or biosimilar drug entrant, or a significant drug price increase).
2. Exclude drugs costing more than a certain amount from the transition requirements and otherwise work to pare back these requirements (e.g., with respect to long-term care facilities).
3. Allow plans/PBMs to contract with an accredited specialty pharmacy network;
4. Retract the recent CMS policy that requires exceptions to be approved to the lowest applicable tier.
5. Modify policies on biosimilar coverage both in the Medicare Coverage Gap Discount Program and for copayment levels for LIS beneficiaries in the Initial Coverage Phase, and adopt policies that facilitate inclusion of biosimilars in Part D formularies.

6. Allow plans/PBMs to place new high-cost drugs into the specialty tier based on expected costs of over $670, rather than forcing Part D plans/PBMs to justify that the cost is over $670 based on actual claims data, which is unavailable because the drug is new.
7. Limit protected classes as proposed in 2015 NPRM which was subsequently withdrawn on May 23, 2014, (see http://www.gpo.gov/fdsys/pkg/FR-2014-05-23/pdf/2014-11734.pdf)
8. Allow plans to provide coverage for only a 15-day supply for a first fill of a specialty drug to make sure the patient can tolerate the medication.

ii. Use of Trump administration executive orders

1. Series of executive orders (EOs) released with goal of ensuring that regulatory agencies are regulating to minimize economic burdens (see https://www.whitehouse.gov/briefing-room/presidential-actions/executive-orders)
2. EOs could possibly be used to revise or retract rules that are barriers to lowering drug prices

iii. IPAB and CMMI – Both entities created under ACA

1. IPAB (Independent Payment Advisory Board) envisioned as panel to enforce limits of Medicare growth, including changes to drug reimbursement.

a. Never triggered as actuarial threshold not yet met (although that could change this spring)
b. In absence of panel, HHS may carry out IPAB activities
c. Lots of efforts to revoke but looming out there with broad authority to cut drug prices

2. CMMI (Centers for Medicare and Medicaid Innovation)
    a. Established to experiment with new approaches to paying for drugs and services to lower costs while keeping/improving quality of care
    b. Broad authority, not challengeable in court
    c. Assess options for moving drugs that currently can be covered in either Part B or D, into Part D.
    d. Assess options for applying PBM utilization management tools used in Part D, to drug coverage under Part B.

l. MedPAC Proposals

i. Part D reinsurance (Formally recommended in MedPAC June 2016 report at http://www.medpac.gov/docs/default-source/reports/chapter-6-improving-medicare-part-d-june-2016-report-.pdf?sfvrsn=0)

1. Due to high cost and numbers of enrollees entering the coverage gap, Part D should be changed to transition Medicare's reinsurance from 80% to 20% of catastrophic spending.

2. Manufacturers' discounts in the coverage gap should no longer count towards enrollees' true out-of-pocket (OOP) spending.
3. Cost-sharing above the OOP threshold would be eliminated.
4. Plans/PBMs would have more flexibility to use formulary tools.

ii. Part B Drug Value Program (DVP) – Voted into recommendation but not yet published (presumably it will be in June 2017 report)

1. Builds off of the Competitive Acquisition Program (CAP) created in MMA, which called for third-party non-profits to buy drugs and sell them to physicians, program never implemented.
2. Under DVP, which would be in place by 2022, Medicare would contract with small number of private vendors to negotiate drug prices less than drug's ASP.
    a. Vendors could use formularies and binding arbitration in certain cases.
    b. Providers would buy drugs from vendors at the negotiated price.
    c. Medicare would reimburse at the uniform price plus an administrative fee.
    d. Details to be provided in June recommendations but pushback already fierce.

m. Other ideas under consideration based on publically available reports on Trump administration discussions with industry.[1]

   i. Change Medicaid so not all FDA approved drugs need to be covered

   ii. Require faster generic approvals from FDA

   iii. Revisit orphan drug incentives to ensure they are used to develop medicines to treat rare diseases, not as gateway to premium prices and huge sales beyond orphan indications.

   iv. Reform outdated laws that prevent outcomes-based contracting and otherwise encourage value-based arrangements

   v. Revise current reimbursement policy for biosimilars in Medicare Part B since all biosimilars referencing the same innovator drug are paid under same reimbursement code

   vi. Eliminate brand abuses in REMs (Risk Evaluation and Mitigation Strategies) and other restricted distribution systems to facilitate generic competition

   vii. Mandate pass-through of rebates at POS under Medicare Part D[2]

      1. Currently allowed but very little usage due to risks of having to estimate rebates at POS

[1] See, e.g., Cathy Kelly, "HHS Action on Drug Pricing: Here's Who Secretary Price is Listening To", Pink Sheet, May 25, 2017.

[2] Health Care Policy and Law, "Association of Prescription Drug Price Rebates in Medicare Part D With Patient Out-of-Pocket and Federal Spending," May 30, 2017, http://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2629497

2. Administration reportedly interested in concept, and could conceivably provide incentive such as highlighting plans that offers POS rebates, in marketing materials
3. Concerns that mandatory rebates may help only the few enrollees with high OOP, but lead to premium increases across the board as well as higher government subsidies

V. Conclusion

a. There are currently multiple issues confronting policy makers regarding pharmaceutical pricing.
b. These issues are far more complex than simply criticisms over high drug costs.
c. The Administration is likely to advance some administrative (i.e., regulatory) proposals this summer, and Congress may act later this year.
d. These issues are likely to linger into the year ahead and possibly even longer, as they affect every public health insurance program in the United States.