AAPS News April 2018: Safe Kickbacks

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The leading publication of organized medicine has published an extensive analysis of U.S. "health care" spending, which is twice as high per capita as in other comparable countries—although health outcomes are no better, and utilization is similar (Papanicolas et al. *JAMA* 3/13/18). Why?

"It's the prices, stupid!" editorializes Ezekiel Emanuel, M.D., Ph.D., quoting the late Uwe Reinhardt, Ph.D., one of the longest-tenured members (25 years) of *JAMA*'s editorial board.

Doctors' pay is claimed to be higher in the U.S. (see p 2). Administrative costs account for 8% of U.S. health care spending, vs. 1% to 5% in the other

countries. Another huge factor is that drugs and devices cost two or three or even 10 times more here.

Drug Pricing

In a February 2018 white paper, "Reforming Biopharmaceutical Pricing at Home and Abroad," the Council of Economic Advisers admits: "Reducing drug prices that Americans pay means recognizing that many artificially high prices result from government policies that prevent, rather than foster, healthy price competition. Drug prices, for example, are sometimes artificially high due to government regulations that raise prices" (tinyurl.com/ya62ukd6).

For example, the fixed cost of bringing a new, patented drug to market has increased rapidly, to about $2.6 billion.

The CEA also discusses the high prices induced by Medicare and Medicaid reimbursement policy. Under the Medicaid Drug Rebate Program, states are required to cover a manufacturer's drugs in their Medicaid programs in exchange for discounted rates. In 2014, Medicaid programs spent $42 billion on prescription drugs and collected about $20 billion back in rebates. Manufacturers may inflate prices in the private sector to collect a higher post-rebate price from a large Medicaid customer base.

The pharmaceutical distribution system is highly concentrated and lacks transparency, CEA states. Pharmacy benefit managers (PBMs) act as buying intermediaries between manufacturers and insurance plans. They negotiate rebates off list prices and then pass on some of the benefit to health insurance plans and beneficiaries. Three PBMs account for more than 80% of the market. More than 20% of spending on prescription drugs was taken in as profit by the pharmaceutical distribution system. The size of manufacturer rebates and the percentage of the rebate passed on to health

plans and patients are secret (ibid.).

Monopsony

What *JAMA* ignores but CEA alludes to is the powerful buyers' monopoly (monopsony) that is estimated to add $200 billion of unnecessary spending to the U.S. medical system: the Group Purchasing Organization and Pharmacy Benefit (GPO/PBM) cartels. These were originally intended to save money.

The first GPO was formed in New York City in 1910 to reduce hospitals' costs by buying supplies in bulk. Under a cooperative business model, members paid dues to cover administrative costs, which by design were less than the savings from bulk discounts. This model worked well for 80 years.

In 1986 and 1987, Congress enacted the Safe Harbor provision (see p 3) exempting GPOs from criminal prosecution for taking kickbacks from suppliers. After the Inspector General of the Dept. of Health and Human Services (Richard Kusserow from 1980-1992) implemented the provision in 1991, vendors and not hospitals began paying GPO "administrative" expenses, which were never supposed to exceed 3% of sales. Now GPOs extract a wide range of fees from the medical supply chain for the "privilege" of access to the market. Kickbacks (a.k.a. rebates, sharebacks, etc.) often exceed 50% of a supplier's revenue for a single drug. The HHS IG office has not exerted its oversight authority in years.

PBMs also are claiming coverage under anti-kickback safe harbors in order to assert control over outpatient drugs and devices. Their excessive fees and stranglehold over access has resulted in shortages of basic life-saving drugs, exorbitant prices, and quality problems, according to Physicians against Drug Shortages (PADS, **https://tinyurl.com/yaq5lhau**). Sole-

source contracts, not Hurricane Maria, are responsible for gutting domestic supply capacity, writes Robert Campbell, M.D., of PADS.

Four giant GPOs control about 90% of annual contracting volume: Vizient, Premier, HealthTrust and Intalere. The big three PBMs, which control more than 70% of all prescriptions dispensed in the U.S., are UnitedHealth Group, CVS Caremark, and Express Scripts.

The American College of Emergency Physicians (ACEP) and the Association of Mature American Citizens (AMAC) are among groups supporting the repeal of the Safe Harbor for the GPO/PBM cartel. Supporters of this Safe Harbor include Richard Kusserow (see p 2), CEO of Strategic Management, which he founded on leaving HHS. He argues that any risks could be addressed through regulatory requirements of disclosure, reporting, and transparency (**https://tinyurl.com/yawh83vz**).

The Trump Administration has expressed concern about drug prices. FDA Commissioner Scott Gottlieb has criticized PBMs (**https://tinyurl.com/y9up8lbf**). The Dept. of Justice is probing generic drug price fixing (**https://tinyurl.com/y7ebjo39**). Less encouraging is that HHS Secretary Alex Azar has chosen CVS Caremark VP Daniel Best to head the effort.

Public-private collusion is anathema to free markets.

Safe Harbors

In an attempt to combat fraud and abuse in the Medicare and Medicaid programs, the anti-kickback statute, passed in 1972 and strengthened in 1977 (42 U.S.C. 1320a-7b(b), **tinyurl.com/y9px996t**), provides civil and criminal penalties for individuals or entities that "knowingly and willfully offer, pay, solicit or receive remuneration in order to induce business

reimbursed under the Medicare or State health care programs," or to "induce the purchasing, leasing, ordering, or arranging for any good, facility, service, or item paid for by Medicare or State health care programs." Remuneration includes kickbacks, bribes, and rebates made directly or indirectly, overtly or covertly, or in cash or in kind.

Today, criminal penalties can include fines up to $100,000 and a 10-year prison term per kickback while civil penalties can cost as much as $100,000 per kickback plus three times the amount of the damages sustained by the government. Violators can also be excluded from federal healthcare programs.

Since the statute was so broad, Congress directed HHS to issue regulations designating safe harbors for various payment and business practices that would be protected from enforcement, explains AAPS president-elect Marilyn Singleton, M.D., J.D. The GPO safe harbor was put in place in 1986 and 1987 (P.L. 99-509 & P.L. 100-93).

There were are 13 "safe harbor" exemptions to the anti-kickback statute in 1999 (**tinyurl.com/y7ran24e**), and now more than 20 published in the Code of Federal Regulations [(42 CFR 1001.952—Exceptions), **https://tinyurl.com/y739nw49**]. Most are physician-friendly, involving space or equipment rental, personal or referral services, recruitment, malpractice insurance subsidies for obstetricians, ambulatory surgery centers, etc. None of these have been shown to inflate medical costs. But the GPO/PBM safe harbor is the "mother of all safe harbors" and "the biggest creature in the swamp," according to anesthesiologist Robert Campbell, M.D. He states it is the primary reason for lack of local anesthetics in his hospital for spinal anesthesia, the safest method for women undergoing Caesarean section. It also explains why patients must pay $400 for insulin that costs $18 to manufacture.

The criteria for allowing a safe harbor consider the effects of a payment practice on access to medical services, quality of services, patient freedom of choice, competition, costs to federal healthcare programs, and potential overutilization (**https://tinyurl.com/y7k5tska**). It appears that GPOs and PBMs no longer meet these criteria. A 2014 Government Accountability Office (GAO) report concluded that the GPO funding structure involves an inherent conflict of interest (**tinyurl.com/y78csn27**). It noted that while the Federal Trade Commission (FTC) continues to receive complaints about GPO contracting practices, it has not initiated any enforcement actions against them in the last 10 years. GAO only recommends that HHS check for appropriate reporting of hospitals' administrative fee revenues to Medicare.

The federal government allows PBM rebates in the belief that such rebates might lower its drug costs. However, a rebate is really a higher price to patients at the pharmacy level. The manufacturer benefits from those higher prices and shares with the PBM.

Payment Disparities

That "prices convey important signals," pointed out by Friedrich Hayek in 1945, has now been cited in *JAMA*. Prices that are artificially high or low lead to widespread underuse or overuse, state Austin Frakt, Ph.D., of Boston University School of Public Health and Michael Chernew, Ph.D., of Harvard Medical School (*JAMA* 2/6/18). Medicare's policy of paying much more for procedures performed in hospital-owned facilities encourages hospitals to buy up physician practices. The Medicare Payment Advisory Commission and other organizations routinely call for site-neutral payments, but politically powerful stakeholders, such as hospitals that built business models based on existing price distortions, vigorously oppose reform.

Medicare's Physician Value-Based Payment Modifier (PVBM) program likely exacerbates disparities in patient care by "literally taking money from providers that serve the poor and giving it to providers that serve the rich." The incentives are "all in the direction of getting the easiest-to-manage patients" (*JAMA* 3/13/18).

Conspiracy of Silence

Americans are not aware that they may be paying $1 trillion a year too much for medical care and could benefit from major changes in the way they purchase it, writes Clark Havighurst, professor emeritus of law at Duke University (*WSJ* 2/8/18). While mentioning the need to slow cost increases, politicians claim the main problem is lack of coverage. "The health-care industry picks consumers' pockets mostly without the victims realizing it" because of the tax treatment of employer-owned health insurance. Workers do not know the cost in lost pay. Employers and labor unions seem to find it advantageous to confer increasingly generous benefits—that workers unwittingly pay for themselves. The tax subsidy is projected to cost $4 trillion in lost payroll and income tax revenue between 2016 and 2025. Havighurst hopes that the nonprofit joint venture by Amazon, Berkshire Hathaway, and J.P. Morgan to address excessive spending, starting with their own employees, will help to ignite a national discussion.

Flashback: Kusserow Wins AAPS Award

In 1990, at the 47th annual meeting in Scottsdale, Richard Kusserow, then HHS Inspector General, received the highly competitive Bureaucrat of the Year Award. His greatest distinction was initiating the bounty system that awarded merit-pay increases to agents based on the number of sanctions imposed on physicians for alleged fraud. His office claimed that the requirement for an agent to complete *x* number of sanctions was "not a

quota [but] a measure of a person's effectiveness" (aapsonline.org/newsletters/nov90.htm). Another Kusserow idea was to "roll in" the average Medicare payment for laboratory tests ($13.50 per visit) to the fee for the visit, and reduce overutilization and Medicare administrative costs by expecting physicians to pay for all lab testing (http://aapsonline.org/newsletters/feb91.htm).

"Americans spend up to $378 billion annually in tax-related accounting costs, and…6 billion hours complying with the tax code…equivalent to the annual hours…of a workforce of 3.4 million."
Walter E. Williams, 2017, tinyurl.com/y9pa3em4

Physician Compensation in Perspective

Although it is stated in the Mar 13 issue of *JAMA* (see p 1) that both specialists and generalists in the U.S. are paid about twice as much as in comparable countries, and that the average difference in compensation is "more than $200,000" (Papanicolas et al.), the proportion of health spending allotted to physician compensation in the U.S. is the second lowest among Western countries with modern health systems. According to data from the Overseas Employment Development Board and a survey from healthcare staffing firm Jackson Healthcare, physician compensation accounted for 8.6% of total healthcare costs in the U.S. in 2011—or $216 billion of the $2.5 trillion spent on healthcare. This proportion is 8.5% in Sweden, 15% in Germany, 116% in Australia, 11% in France, and 9.7% in the UK (tinyurl.com/ya9qu98r).

"At eight percent of total healthcare costs, if physicians worked for free we would still have a serious cost problem," said Richard L. Jackson, chairman and chief executive officer of Jackson Healthcare (https://tinyurl.com/y7lds35a).

U.S. physicians, unlike others, may have a $300,000-$400,000 debt to retire for their medical education.

Not a New Question

In the very first opinion poll of its members, in 1948, AAPS asked: "Should AAPS foster a program to have all localities and states enact legislation to make rebating by both doctors and supply houses a misdemeanor?" Of the 51% who said "yes," 9% said they "wished" medicine could do its own policing because "already there are too many laws"; 49% said "no," "many emphatically." The poll was not intended to establish AAPS policy, but simply to find out and communicate what doctors thought (AAPS *News Letter*, 6/8/1948, vol. 2, no. 4).

Tennessee, Washington Pass Anti-MOC Laws

Awaiting the governor's signature is S.B. 1824, which was passed unanimously by both chambers of the Tennessee legislature. It has strong provisions blocking MOC® requirements for insurance participation and also some protections against MOC® requirements in hospitals.

Ken Lee, M.D., reports that Gov. Inslee of Washington will sign a bill that bans MOC® as a condition of M.D./D.O. licensure. Resolutions he introduced to the state medical association were the basis for this law.

AAPS tracks legislation at **https://bit.ly/mocbills**.

AAPS Calendar

Apr 6. Thrive Not Just Survive and board meeting, Atlanta, GA
Apr 21. Missouri chapter meeting, Independence, MO
May 19. Texas chapter meeting, San Antonio, TX
Oct. 3-6. 75th annual meeting, Indianapolis, IN

ACTION OF THE MONTH

Spread the word about the AAPS 75th annual meeting scholarship essay contest for medical students and residents: top prize $500. See http://aapsonline.org/essaycontest.

Tip of the Month: Providing free samples of scheduled drugs can have unintended consequences if you don't follow the myriad rules and regulations to a "T." A doctor recently lost his privileges for prescribing these drugs after failing to comply with minor provisions related to keeping sample-closet logs.

Illinois Law Violates Freedom of Conscience

In a letter to the HHS Office of Civil Rights, Thomas Olp, Counsel to the Thomas More Society, complains that Illinois P.A. 99-690 violates federal laws enacted to protect the right to decline to participate in or promote abortion. The American Association of Pro-Life Obstetricians and Gynecologists (AAPLOG) state that the law compels medical professionals to discuss the supposed benefits of abortion and to refer for abortion, or at least to supply a list of abortion providers. AAPLOG argues that the law compels speech and is viewpoint discriminatory.

TMB Loses; Attacks Administrative Law Judge

Administrative law judges (ALJs) in the State Office of Administrative Hearings (SOAH) are supposed to enjoy "decisional independence." Yet in the past decade, the rate of dismissals of Texas Medical Board actions has been 1%. Fear of career-ending reprisals could reduce the rate to zero.

In September, Judge Hunter Burkhalter, after a week-long hearing, ruled in the case of *TMB v. Dr. Robert van Boven* that there was insufficient and

unpersuasive evidence of the charges. TMB reluctantly accepted the ruling, rather than appealing it to state district court, meanwhile impugning his partiality and suggesting that a different judge, perhaps a female judge, might have decided differently. Then Judge Burkhalter was forced to resign, or be terminated, apparently based on a complaint by TMB interim director Scott Freshour. Chief ALJ Lesli G. Ginn has forbidden SOAH staff, including 30 ALJs, to speak to the media.

Former SOAH ALJ Tommy Broyles, wrote, in email correspondence to the Austin *Chronicle*: "ALJs…are the independent gatekeepers of the enormous power of the state to interfere in the lives of the citizens of Texas. Citizens have a Constitutional due process right to a fair and unbiased hearing when the state is attempting to take away one's right to work or to otherwise enjoy the liberties we all share. If a state agency—who is party to a hearing—may contact and influence the decision makers or their chain of command, then the entire system is rigged for the state. Citizens stand no chance at defending themselves against powerful state agencies…" (**https://tinyurl.com/y75wbcaa**).

Regulatory Compliance Costs $39 Billion

Hospitals, health systems, and post-acute care (PAC) entities spend $39 billion per year complying with 629 discrete regulatory requirements, according to the American Hospital Association (**https://tinyurl.com/yapd9za2**). An average-size hospital dedicates 59 FTEs, one-quarter of whom are doctors or nurses, to regulatory compliance. More than two-thirds of FTEs involve conditions of participation and billing/coverage verification. Meaningful-Use requirements cost an average of $760,000/y and MU-related computer systems upgrades $411,000/y. The administrative aspects of "quality" reporting cost $709,000/y and are especially onerous for entities involved in "value-

based" purchasing models. The patient benefit from these duplicative and inefficient processes is "unknown." Frequent regulatory changes are costly and disruptive. The Stark Law and Anti-Kickback Statute can impede innovation, as waivers from fraud-and-abuse laws for demonstration projects cannot be extended beyond the project.

CORRESPONDENCE

The "Facility Fee" Scam. We were aware of the Medicare scheme that enriches hospitals when hospital-employed physicians perform procedures in hospital-owned out-patient facilities. This scam helped to drive the shift from independent to hospital-owned practices and physician employment. As most physician employees' pay is linked to Relative Value Unit productivity, they are heavily incentivized to perform more procedures. Now we have results of a study that quantitates just how much more hospitals have been allowed to charge than independent physicians: $2.7 billion more in 3 years for just four procedures: colonoscopies, echocardiograms, cardiac catheterizations, and arthrocentesis. Medicare patients themselves owed $411 million more as a result (*MedScape* 11/16/17, **https://tinyurl.com/yb29vgf3**).

Lawrence R. Huntoon, M.D., Ph.D., Lake View, NY

A Model for Price Transparency. Britain has long had an active cash market for medical care provided in private hospitals, such as Nuffield Hospitals (**https://tinyurl.com/ybygq7h9**). This helps patients get around the long waiting lists for care in National Health Service hospitals and also serves patients from abroad. Nuffield offers all-inclusive prices and will match competitors' prices under reasonable condition. The Hospital Corporation of America (HCA) also offers a price list for self-pay UK residents at its UK hospitals. Prices (in 2015) for an open inguinal hernia

repair were $4,451 at HCA UK and $3,060 at Surgery Center of Oklahoma; for hip replacement, $17,655 vs. $19,400.

Linda Gorman, Ph.D., Independence Institute

MACRA. At a recent Wharton School conference, a panel of CMS experts admitted to having *no knowledge* of how much had been or will be spent implementing MACRA, and *no proof* that it will either save Medicare money or improve value to patients.

Marion Mass, M.D., Sellersville, PA

The Legacy of Abortion in China. An essay by Jeff Koloze, "Literary Analysis of Abortion in the Short Story 'Explosions' by Mo Yan," reflects on the one-child policy and forced abortions in the People's Republic of China (**tinyurl.com/ybajpk8q**). Koloze states that today there are 8–13 million abortions and 20 million live births per year, with 120 boys born for every 100 girls. China now has 38 million more men than women born after 1980. How does it affect your perception of your existence to know that nearly half of your birthmates were murdered? Are you more subservient to the state in gratitude for being allowed to live?

Samuel Nigro, M.D., Cleveland Heights, OH

MOC and Extortion. Until the American Board of Medical Specialties returns to life-long certification, its brand will be tarnished by the extortion factor. Maintenance of Certification® cannot be truly voluntary or demonstrate a meaningful commitment to lifelong education or professionalism until it must compete on the open market with all forms of continuing medical education, without the threat of decertification.

Paul Martin Kempen, M.D., Ph.D., Weirton, WV

"Bundling" for "Value." The idea of the Diagnosis-Related Group, I'm told, originated with R. B. Fetter, M.D., and J.D. Thompson, M.D., at Yale as they scribbled on the back of a napkin after a few beers. The exercise in DRG bundling is a now an institutionalized mishmash of hospital utilization data and *assumptions of health care value* (see **https://tinyurl.com/yafzczsz**). Quantifying the value of anything depends on the point of view of the observer (or funder). So, prospectively teasing out an *individual* case in the hospital DRG swamp is, by design, virtually impossible.

Lee Beecher, M.D., Maple Grove, MN

Pre-authorization Insanity. This week I had to, for the first time, get pre-authorization for test strips for a diabetic through Medicare Part D. It took 6 minutes to do the form; doing ten would take an hour away from patient care. The test strips cost $9.95. Without the form, the patient would have to pay $495.

Gene Uzawa Dorio, M.D. , Santa Clarita, CA

Why ACA Needs to Be Killed—in One Chart. A graph of average annual health insurance costs for family coverage, with deductibles stacked on top of premiums, shows a huge discontinuity between 2013 and 2014, when ObamaCare went into effect. The total leapt from less than $10,000 to more than $15,000. Then, in 2014 not only did costs grow but the rate of growth increased, with the total exceeding $20,000 in 2017 (tinyurl.com/y7h87g6q). This robs middle-class Americans of disposable income and puts many under acute financial pressure. It puts an albatross around the neck of the economy by diverting huge sums to one group of industries at the expense of others. It helps explain why so many Americans cannot find meaningful work. And yet Republicans are itching to save ObamaCare by passing huge subsidies for insurers that lose money in the

exchanges.

This is the cost of supporting a Party that does not even remotely require its elected officials to adhere to or share any kind of coherent governing philosophy. They are a bunch of free-lancers who primarily protect themselves, and often get sold to the highest bidder.

Joseph Guarino, M.D., Reidsville, N