

Pre-Publication Draft

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PAYING PHYSICIANS FOR CANCER CARE

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Approximately 14 million individuals in the United States are currently living with cancer; nearly 2 million Americans are newly diagnosed with cancer each year.¹ Because cancer is a disease of aging, the fact that the baby boomers are getting older will contribute to the volume of health care services to be delivered to treat cancer in the near term. Still further, the age at which cancer is diagnosed is predominately in people between 64 and 74 years of age.² On that basis, considering how Medicare pays for cancer care is a key to whether the services provided, in fact, are valuable – of high quality at contained cost.

In 2018, there were 12,400+ hematologists, hematologists/oncologists and medical oncologists found in the Medicare Physician Compare database, used by the American Society of Clinical Oncology (“ASCO”) to assess “The State of Oncology Practice in America, 2018: Results of the ASCO Practice Census Survey”³. Other sources report there are more than 20,000 oncologists actively practicing nationally.⁴ Most oncology practices are single specialty; and most are small, employing one to five oncologists. Whichever source you believe, the number of oncologists is not that high by comparison with surgeons (53,002) and radiologists (47,828); but even measured against an internal medicine subspecialty, there are significantly fewer oncologists than cardiologists in active practice in 2019 (32,640).⁵

Yet, this relatively small cohort of physicians is responsible for a large portion of our national health care expenditures, in their treatment of their cancer patients, offering infused and oral drugs in the office, as well as referrals for surgery, radiation therapy and more. Nationally, for all cancers in the United States, the monies spent on treatment in 2017 were \$147.3 billion,⁶ out of \$3.5 trillion spent on all of health care in 2017 and higher still in 2018,⁷ expected to be \$174 billion by 2020.⁸ By comparison, expenditures on heart disease *and* stroke in 2018 was \$199 billion.⁹ Of the more than \$3 trillion spent, \$694 billion was spent on physicians and clinic services, as opposed to hospitals and nursing homes, for example, and fully an additional 50% of that (\$337 billion) was spent on prescription drugs. In 2017, one sixth of expenditures for all prescription drugs in the United States. was spent on cancer drugs (\$50 billion)¹⁰. As significant as that number is, the pace of innovation and introduction of new drugs has far outstripped historical expenditures in part because, not only has almost every new cancer drug introduced since 2014 cost more than \$100,000 a year,¹¹ in 2017 more than one alone cost \$400,000 per

¹ “SEER Cancer Statistics Review (CSR) 1975-2014,” National Cancer Institute, updated April 2, 2018.

² “Age and Cancer Risk”, National Cancer Institute, <https://www.cancer.gov/about-cancer/causes-prevention/risk/age> Accessed 10/13/2019

³ Kirkwood et al, “The State of Oncology Practice in America 2018”, *Journal of Onc Prctc*, (July h 2018) <https://ascopubs.org/doi/pdf/10.1200/JOP.18.00149> (accessed 11-11-2019) Obviously the Medicare database would exclude most pediatric hematologists and oncologists.

⁴ <https://www.statista.com/statistics/209424/us-number-of-active-physicians-by-specialty-area/> accessed 10-14-2019

⁵ <https://www.statista.com/statistics/209424/us-number-of-active-physicians-by-specialty-area/> accessed 10-14-2019

⁷ <https://www.cancer.gov/about-cancer/understanding/statistics> Accessed 10-17-2019

⁸ <https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/nationalhealthexpenddata/nhe-fact-sheet.html> accessed 10-14-2019

⁹ <https://www.cdc.gov/chronicdisease/about/costs/index.htm>

⁹ Id

¹⁰ <https://www.fdanews.com/articles/186980-us-cancer-drug-spending-nearly-doubled-from-2017-iqvia> accessed 10-17-2019

¹¹ Fox, “Cancer Drug Spending doubled in the last 5 years according to report,” May 24, 2018

<https://www.nbcnews.com/health/health-news/cancer-drug-spending-doubles-5-years-n877236> Accessed 10-17-2019

year.¹² And every single one of those drugs was ordered by a physician and will continue to be so. At the same time, oncologists have long complained that they do not get paid for all the services they provide to patients in their care; and, data has shown that typical fee-for-service payment for physician services rendered to cancer patients only covers 2/3 of the costs of the services provided.¹³ Taken together then, how physicians are paid both for cancer care and cancer drugs is a major issue in containing American health care costs generally. Understanding the incentives in physician reimbursement models is critical to any potential ability to manage this growing challenge, while providing patients with optimal care.

1. *The Drug Perversion*

The single most striking aspect of the way in which cancer care is paid for is that traditionally, for more than sixty years, physicians have been paid for the drugs themselves along with the administration of the drugs (oncolytics) which dominate cancer treatment.¹⁴ When I first began working with oncologists to a significant degree, well more than 25 years ago, I was dumbstruck at the idea that, unlike cardiologists or surgeons, they made a good portion of their incomes by being paid for the drugs which they administered to their patients. It has long been a mystery to me, now solved, as to how this arose. I am not alone, as we will see, in my policy concerns regarding the persistence of this model.

In the 1940s, mustard gas which had been used in biological warfare was found to be useful in treating Hodgkin's disease. But the toxicity and dynamic nature of the substance required special training to deploy it. Physicians developed the skills and training to manage the administration of the drug. As other chemotherapeutic agents, which were themselves toxic if not administered properly, were developed, physicians bought them wholesale and administered them to patients. By the 1970s, there were still only about a dozen chemotherapeutic agents available; and their costs were minimal.

As Medicare expanded, the 'physician administered drugs' were a component of the Part B benefit as opposed to a pharmacy benefit. The model was for physicians to purchase the drugs, manage inventory of them, administer drugs in the office and submit claims for reimbursement of the drugs themselves and their administration. Physicians were reimbursed under Medicare at a percentage of a drug's average wholesale price (AWP) as published by manufacturers and

¹² Rimer, "The Imperative of Addressing Cancer Drug Cost and Value", Mar 15, 2018, <https://www.cancer.gov/news-events/cancer-currents-blog/2018/presidents-cancer-panel-drug-prices> Accessed 10-18-2019

¹³ Towle, Barr and Senese, "The National Practice Benchmark for Oncology. 2014 Report on 2013 Data, *J of Oncology Practice* (Nov. 2014) <https://ascopubs.org/doi/pdf/10.1200/jop.2014.001826> (accessed 12-12-2019)

¹⁴ For a review of the history of paying physicians for cancer drugs see, "ASCO in Action Brief: Physician Administered Drugs – The Evolution of Buy & Bill," (February 22, 2013) <https://www.asco.org/advocacy-policy/asco-in-action/asco-action-brief-physician-administered-drugs-%E2%80%94-evolution-buy-bill>; Pearl, "Oncologist pay and chemotherapy: Buy and bill needs to stop," (Aug 19, 2014) <https://www.kevinmd.com/blog/2014/08/oncologist-pay-chemotherapy-buy-bill-needs-stop.html>; Bailes and Coleman, "The Long Battle Over payment for Oncology Services in the Office Setting," ASCO (Jan. 2014) <https://www.asco.org/advocacy-policy/asco-in-action/long-battle-over-payment-oncology-services-office-setting>; Polite, Conti and Ward, "Reform of the Buy-and-Bill System for Outpatient Chemotherapy Care is Inevitable: Perspectives from an Economist, a Realpolitik and an Oncologist," (2015) <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4594838/>; all accessed 11/07/2019

tracked in private databases. Commenters analogize this approach to a suggested retail price. But there was variability and non-standardization. Some manufacturers published their wholesale acquisition costs, to which the publishers tracking the drug prices added 20-25%. Until Medicare set payment by regulation at 100% of AWP, about half of the Medicare carriers had paid more than 100% of AWP.

As more agents became available though, there began to be a concern that the model of buying wholesale at a discount and billing at a higher rate did nothing to contain costs. During the 1980s and 1990s most chemotherapy was provided on a hospital inpatient basis. Throughout this time, prior to the publication of the first Medicare Physician Fee Schedule in 1992, oncologists believed they were not adequately paid for their services in administering the drugs, and relied more and more on the difference between the amounts paid to them for the drugs and the price at which they could actually acquire them, to make up the difference. Some have argued that when the Fee Schedule introduced the concept of practice expenses, the problem of inadequate recognition of the expenses in administering and managing the drugs would have been solved, but, in fact, it was not even addressed.

During the ensuing 10 years, while there were a variety of proposals floated to address the drug administration versus drug cost problem, nothing was adopted. The fundamental problem was exacerbated as well by legislation in 1993 requiring Medicare to pay for all uses of drugs in chemotherapy regimens if the uses were listed in the monographs of specified compendia, even if they were off label uses as far as the FDA was concerned. Finally, after the Medicare Modernization Act, the model was changed to reflect average sales price (ASP) plus 6%. When the sequestration of 2% went into effect, the result was to pay physicians essentially ASP plus 4.3%.

The model has been criticized as incentivizing the prescription of more expensive drugs so physicians can make more profit on the difference between the actual price at which they obtain the drugs and the payment rate which encompasses average sales price and not actual sales price. It has also been criticized as being inconsistent with reality because of the lag time in developing the information upon which the calculation is based. CMS posts a new ASP for each drug every quarter based on information submitted by drug manufacturers fully six months earlier. There has been additional criticism that this lag has perversely affected the supply of generic oncolytics that are typically less expensive.¹⁵ The argument there is that for generic drug manufacturers who would seek to pass along the prices of raw material acquisition costs or costs of manufacturing and distributing the drugs, the lag time in developing the ASP puts them at risk for those costs. Commercial payors were reportedly slower to adopt the ASP model and typically have paid even more than ASP plus 6% for the drugs. The ASP is also said to favor those practices with substantial purchasing power.¹⁶

¹⁵ See, Polite, Conti and Ward, *supra* n.14

¹⁶ These would include institutions who are eligible for Medicare's 340B program which was originally designed to put a cap on the amounts drug manufacturers could charge to institutions which served poor and underserved patient populations. See, MedPac "Overview of the 340B Drug Pricing Program", (May 2015) <http://medpac.gov/docs/default-source/reports/may-2015-report-to-the-congress-overview-of-the-340b-drug-pricing-program.pdf?sfvrsn=0> (accessed 11/08/2019). It, too, has been criticized because there is no requirement to pass along the discounts received; there is no restriction on which patients' drugs are subject to the discount, so hospitals and federally qualified health centers which benefit from the program are paid the same way physicians are paid

Some data has indicated that oncologists charge significantly more than their colleagues who also deliver ‘physician-administered drugs.’ Median charges were 9-51% higher at the oncologist office than other specialty offices.¹⁷ By contrast, hospitals actually receive a far larger share of the profits on drugs than physicians do. Hospitals served 53% of patients receiving physician-administered drugs in 2018, while physician offices treated 47% of patients in the commercial market but retained only 9% of gross margins.¹⁸ Physician advocates counter the accusation of perverse financial incentives as motivating improper prescribing.¹⁹ They argue that the studies typically relied on to substantiate the effect of the incentives are outdated. Practices, they contend, lose money for 21% of all Part B drugs. “Among the top 10 highest cost cancer drugs, which account for 72% of all cancer drugs and 23% of all Part B drugs in terms of total Medicare spending in 2016, the average estimated difference between drug acquisition cost and Medicare allowable payment amount is 2.4%, or \$2.50.”²⁰ More recent studies, they argue, substantiate that overall treatment choice is not driven by the opportunity to make financial margin on drugs; and, the overall expenses associated with services required to deliver quality oncology care go well beyond drug administration, and are still not reimbursed effectively, including patient and family counseling, nutrition advice, care coordination with other providers, palliative care, telephone support, financial counseling and other services that assist cancer patients with their treatment.

As these battles have continued to wage, variations on the “buy-and-bill” model have also emerged. “White bagging” occurs where a specialty pharmacy ships a patient’s prescription directly to the physician office, which holds the drugs to administer during the patient’s appointment. “Brown bagging” occurs where the patient picks up a prescription at a pharmacy and takes it to a physician’s office for administration. In both of these models, the pharmacy gets paid for the drugs it dispenses, while the physician continues to be paid for the administration of the drugs. It is reported that this model has supplanted buy-and-bill for about one quarter of cancer drugs.²¹ Both models have been criticized as having developed primarily at the behest of insurers.²² But providers have also questioned the increased potential for mishandling of drugs, additional administrative time for separate approval both of the drugs and their administration, questionable provenance of drugs, safety, and potentially higher costs. ASCO is opposed to both

without availability of the discounts. This creates an even larger gap between the cost of drugs and the amounts paid for them. The program is the topic of a variety of reform efforts as well, (See, Conti, et al, “Proposed Reforms To The 340B Drug Discount Program”, [Health Affairs Blog](#) (March 7, 2018) <https://www.healthaffairs.org/doi/10.1377/hblog20180306.70004/full/> (accessed 11/8/2019). But that program is beyond the scope of what is being addressed here.

¹⁷ See, LaPointe, “Oncologists Charge 9-51% More for Physician-Administered Drugs”, (March 27, 2018) <https://revcycleintelligence.com/news/oncologists-charge-9-to-51-more-for-physician-administered-drugs>

¹⁸ La Pointe, “Hospitals Retain 91% of Profit from Physician-Administered Drugs,” (Sept 17, 2019) <https://revcycleintelligence.com/news/hospitals-retain-91-of-profit-from-physician-administered-drugs>(accessed 11/8/2019)

¹⁹ Community Oncology Alliance, “The Myth of Perverse Physician Incentives,” (Dec 31, 2018) <https://www.communityoncology.org/the-myth-of-perverse-physician-incentives/> (accessed 11-8-2019)

²⁰ Id at 2.

²¹ “How Specialty Pharmacy Is Penetrating Buy-and-Bill Oncology Channels,” (July 26, 2016), <https://www.drugchannels.net/2016/07/how-specialty-pharmacy-is-penetrating.html> (accessed 11-8-2019)

²² Brousse, “Brown And White-Bagging: A Disturbing Medication Trend,” (June 3, 2014) <https://www.nerdwallet.com/blog/health/brown-whitebagging-disturbing-medication-trend/> (accessed 11-8-2019)

practices, in part, because they assert it is a clinically flawed approach when patients may need their medications adjusted as of the day of administration.²³

The persistence of the buy-and-bill model is troubling to a host of policymakers. When pharmaceutical manufacturers offer discounted rates to physicians, there doesn't seem to be any logic to the physicians marking up those acquisition costs. My astonishment at encountering this phenomenon years ago is met today by continued astonishment that this model exists at all. The real problem is that payers, including Medicare, have never paid oncologists adequately for all the services that they perform in caring for cancer patients. If they were paid a fair fee for the services they actually do render, then the discounted rates offered by pharmaceutical manufacturers to them could become the real price, paid by insurance. Before examining efforts to modify the physician payment model to pay fairly and create real value, the special problem of the cost of cancer drugs should be considered in the context of how physicians are paid for cancer care.

2. *The Drug Cost Challenge*

As the opening of this article noted, the cost of oncolytic drugs has risen at a pace that exceeds the widespread problem of increased drug prices throughout the healthcare system. While the Part D benefit under Medicare forbids negotiation over prices by the government²⁴, the physician administered drugs at issue in cancer care are paid for under the Part B benefit. There are a range of legislative proposals to confront the Part D negotiation prohibition problem, but cancer drugs tend to be treated differently for a variety of reasons.

In cancer care, there has long been a significant emotional component to treatment choices, since, unlike diabetes or asthma or an acute gastritis, the failure to treat effectively typically is fatal, and even with effective treatment might only be life extending. The concern over the inexorable rise in cancer drug prices has been in discussion for at least the last ten years²⁵ while more and more oncolytics, and immunotherapies, and genetic treatments have soared as appropriate treatments for cancer patients. Development costs for these drugs are high. There are rarely competitive products, which creates effective monopolies for each drug introduced, making the generic versions of earlier drugs seem substandard. Efficacy is measured in terms even of days of survival sometimes. The profits the drugs generate for their manufacturers are extraordinary. Major pharmaceutical companies generally report net profits that are more than double those of the average Fortune 500 company.²⁶ When Opdivo, an immunotherapy treatment, became approved for the treatment of lung cancer, shares of Bristol Myers Squibb

²³ ASCO, "Brown Bagging" and "White Bagging" of Chemotherapy Drugs" (May 2016) <https://www.asco.org/sites/new-www.asco.org/files/content-files/advocacy-and-policy/documents/2016-ASCO-Brown-Bagging-White-Bagging-Brief.pdf> (accessed 11-11-2019)

²⁴ SEC. 1860D-11. [42 U.S.C. 1395w-111] (a)

²⁵ See, for example, Siddiqui and Rajkumar, "The High Cost of Cancer Drugs and What We Can Do About It," (October 2012), <http://dx.col.org/10.1016/j.mayoi.2012.07.007>; and Caffrey, "Dr. Peter B. Bach Outlines Framework for Tying Price of Cancer Drugs to Indication, Value," (Oct 6, 2014) AJMC, <https://www.ajmc.com/focus-of-the-week/bach-outlines-framework-for-tying-price-of-cancer-drugs-to-indication-and-value> (accessed 11-9-2019)

²⁶ Bender, "Cost of Cancer Drugs: Something Has To Give," Managed Care (May 3, 2018) <https://www.managedcaremag.com/archives/2018/5/cost-cancer-drugs-something-has-give>

gained 7% and were trading at more than 38 times their expected 2015 earnings.²⁷ In 2014, 9% of all monies spent on prescription drugs in the USA was spent on oncology drugs, with another \$11.1 billion spent on supportive care treatments, even though in 2015 not one oncology drug made it into the list of the 20 most widely prescribed drugs.²⁸

While the rising prices are of deep concern to Medicare policy-makers and insurers who foot most of the bill for these prices, they are not without direct consequences to patients. In 2013, 25% of cancer patients chose not to fill their prescriptions or delayed treatment or only took some of the medicine prescribed.²⁹ Medicare patients with cancer spend on average 11% of their income on treatment, while those without supplemental insurance spend 23% of their income. Ten percent of elderly patients without supplemental insurance spent 60% of their income on cancer expenses in 2014.³⁰ And these data are prior to the introduction of truly expensive treatments.

A number of programs and initiatives have attempted to confront this conundrum. In 2016, CMS introduced a proposed pilot for changing how Medicare would pay for drugs, changing payment from ASP plus 6% to 2.5% plus a flat fee³¹. Both pharmaceutical industry representatives and physicians rose up in arms. The program was abandoned. In a one year pilot program in Florida, UnitedHealthcare introduced a prior authorization program for chemotherapy, but with a wrinkle distinguishing it from most prior authorization programs, which are common in cancer-world. The program introduced a decision support mechanism based on the National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines.³² It was intended to overcome both administrative burden for physicians and an unacceptably high rate of denials of authorization.³³ The rate of authorization increased when the decision support information was deployed; and the speed of review was increased. Still further, the actual costs of care were lowered with an annualized estimated drug savings of \$5.3 million for their Florida plan alone. The conclusion was that it is possible to reduce the cost of cancer therapy using evidence-based decision-making. In contrast, though, a later study of another United initiative, found that in a program where oncologists could opt to receive increased reimbursement from a health plan for less

²⁷ Conti, Berndt and Howard, “Cancer drug prices rise with no end in sight,” (March 25, 2015)

<https://voxeu.org/article/cancer-drug-prices-rise-no-end-sight> (accessed 11-9-2019)

²⁸ Glover, “Oncologists Worry About Rising Costs of Cancer Treatment,” US News & World Rpt (July 1, 2015), <https://news.yahoo.com/oncologists-worry-rising-costs-cancer-treatment-144139278.html> (accessed 11-9-2019)

²⁹ Szabo, “As Drug Costs Soar, People Delay or Skip Cancer Treatments,” NPR, (March 15, 2017)

<https://www.npr.org/sections/health-shots/2017/03/15/520110742/as-drug-costs-soar-people-delay-or-skip-cancer-treatments> (accessed 11-9-2019)

³⁰ Id

³¹ <https://www.npr.org/sections/health-shots/2017/03/15/520110742/as-drug-costs-soar-people-delay-or-skip-cancer-treatments>, See also, Johnson, “This controversial rule could change how doctors profit from using the most expensive drugs,” The Washington Post, (April 11, 2016),

<https://www.washingtonpost.com/news/wonk/wp/2016/04/11/a-controversial-rule-could-change-how-doctors-profit-from-using-the-most-expensive-drugs/>; and, Brennan, “CMS Drops Medicare Part B Drug Payment Pilot,” (Dec 16, 2016), <https://www.raps.org/regulatory-focus/news-articles/2016/12/cms-drops-medicare-part-b-drug-payment-pilot>

³² In the interests of full disclosure, I was outside counsel to NCCN for more than twenty years ending just a few years ago.

³³ See, Newcomer, Weininger and Carlson, “Transforming Prior Authorization to Decision Support,” Journal of Oncology Practice (2016), <https://consultant.uhc.com/assets/journal-of-oncology-practice-transforming-prior-auth-decision-support.pdf> (accessed 11-9-2019)

expensive generic drugs, there was no significant effect on prescribing patterns or costs of care.³⁴ The program was voluntary; and the researchers have suggested that those who chose to participate were already prescribing generic drugs at a higher rate than their colleagues.

A variety of other strategies have been proposed to mediate the draconian effects of these very high cost drugs. Eliminating laws that mandate coverage even for a drug which extends life by .2 months (!) would alleviate some of these problems.³⁵ The same author expands on the United prior authorization exercise to tout its ability to capture far more relevant clinical data about patients in registries so that patients with similarly complex profiles of disease could later be compared in order to help physicians assess optimal therapy for that specific clinical profile. Noting that United's average payment for community physicians was ASP+28% (but for hospitals was an astounding ASP+152%), capping profits to no more than 18%, by regulation, is also proposed. Some have suggested that a good focus to affect cancer drug costs, would be on how the clinical trials are structured which develop the drugs and test them on patients.³⁶ Physicians, they say, should refuse to participate in trials for drugs that are essentially identical to already approved drugs. Others call for designing trials that would produce more data relevant to value, including survival and quality of life over time. Reportedly some payers are introducing outcomes-based contracts, which pay only partial reimbursement if a patient relapses while on the drug at issue. Still other private entities are calculating "value-based" benchmark prices for specialty drugs. The benchmarks are based on evaluation of clinical and cost-effectiveness of new drugs relative to existing treatments.³⁷ To get manufacturer buy in, however, patient access to the less expensive drugs would have to be streamlined, eliminating prior authorizations or step therapy (where a physician must first prescribe a lower priced drug and only move to a higher priced drug if the patient does not respond). Health insurers are struggling to confront the very new forms of treatment including gene therapies which can cost \$2 million per treatment. Some are beginning to offer stop-loss coverage to pick up the employer's cost of coverage above a specified threshold.³⁸ Reportedly CIGNA and CVS-Aetna will be offering such programs in 2020.

One of the real challenges in confronting the effectiveness of cancer drugs under Medicare is a remarkable provision adopted as part of the Affordable Care Act, precluding to the American Federal government the ability to use Quality Adjusted Life Years (QALYs) as a basis for assessing effectiveness of treatments and drugs.³⁹ Virtually every national government everywhere else in the world that conducts effectiveness research and policy uses QALYs to assess appropriateness and effectiveness of care.

³⁴ "Major Payment Reform for Cancer Drugs Falls Short," (May 6, 2019) <https://www.pennmedicine.org/news/news-releases/2019/may/major-payment-reform-program-for-cancer-drugs-falls-short> (accessed 11-9-2019)

³⁵ Newcomer, "Those Who Pay Have a Say": A View on Oncology Drug Pricing and Reimbursement," *The oncologist* (July 1, 2016) <http://theoncologist.alphamedpress.org/content/21/7/779.full> (accessed 11-9-2019)

³⁶ Bender, "Cost of Cancer Drugs: Something Has To Give," *Managed Care* (May 3, 2018) <https://www.managedcaremag.com/archives/2018/5/cost-cancer-drugs-something-has-give>

³⁷ Robinson, "Value-Based Pricing and Patient Access for Specialty Drugs," *JAMA* (June 5, 2018), <https://jamanetwork.com/journals/jama/article-abstract/2680859> (accessed 11-9-2019)

³⁸ Walker and Mathews, "Insurers Pitch New Ways to Pay for Million-Dollar Therapies," *WSJ*, (Sept 5, 2019) <https://www.wsj.com/articles/insurers-pitch-new-ways-to-pay-for-million-dollar-therapies-11567677600> (accessed 11-9-2019)

³⁹ 42 U.S.C. 1320e-1

“QALYs represent health over time as a series of ‘preference-weighted’ health states, where the quality weights reflect the desirability of living in the state, typically from ‘perfect’ health (weighted 1.0) to death (weighted 0.0). Once the weights are obtained for each state, they are multiplied by the time spent in the state; these products are summed to obtain the QALYs.”⁴⁰

But here, out of the same fear of ‘death panels’ and rationing of health care based on science, Congress prohibited the fundamental opportunity of using QALYs for Medicare coverage and reimbursement:

The Secretary shall not use evidence or findings from comparative clinical effectiveness research conducted under section 1181 in determining coverage, reimbursement, or incentive programs under title XVIII in a manner that treats extending the life of an elderly, disabled, or terminally ill individual as of lower value than extending the life of an individual who is younger, nondisabled, or not terminally ill.⁴¹

If all oncolytics and gene therapies and immunotherapies are paid using the same formula, presumably QALYs would not be relevant; but to make any assessment of comparative effectiveness would, in any other circumstance, entail some type of objective judgement such as QALYs. Against a culture of treatment where extension of life by mere weeks assesses a new drug as more effective even though it would cost hundreds of thousands of dollars more, these choices are fraught with difficulty. Still, in the history of the treatment of cancer, when Sidney Farber was treating small children for what was then uniformly fatal leukemia, where he extended their lives, gradually over many trials by days into weeks and then longer, but they still died, we now live in a world where childhood leukemias are almost always curable if found early enough.⁴² So the history of the development of cancer treatment has reflected this tiny, increments of improvement to arrive at far broader results over a longer horizon of measurement. As the American health care world moves more toward demonstrable value of reimbursable care, these challenges will have to be surmounted. Approximately 57% of community oncologists who are being paid on a value-based premise consider prescription drug costs as their top challenge; but they are also increasingly considering the impact of a therapy’s cost, increasing use of care pathways and advancing efforts to predict quality.⁴³ Let us now turn to payment models that are about physician cancer care delivery beyond drugs.

⁴⁰ Neumann and Greenberg, “Is The United States Ready for QALYs?” Vol. 28, No. 5 Health Affairs, 1366-1371 (September/October 2009).

⁴¹ For a longer discussion of this problem and other aspects of measuring value and quality which emerged in the Affordable Care Act, see Gosfield, “The New Value on Provider “Value”, HEALTH LAW HANDBOOK (2011 Ed.) WestGroup, A Thomson Company, pp. 1-34 <https://www.gosfield.com/images/PDF/TheNewValueonValue.pdf> (accessed 11-10-2019)

⁴² Mukherjee, THE EMPEROR OF ALL MALADIES, Scribner (2010)

⁴³ LaPointe, “Prescription Drug Costs Challenge Value-Based Care in Oncology,” (March 21, 2019), <https://revcycleintelligence.com/news/prescription-drug-costs-challenge-value-based-care-in-oncology> (accessed 11-9-2019)

3. Past Commercial Payer Reform Efforts⁴⁴

The persistent problems associated with paying physicians for cancer care have been the subject of a litany of reform attempts. In 2011 Peter Bach, a long-standing critic of compensation for cancer care, with his colleagues, proposed an episode-based payment for cancer care for Medicare, basing payment on average costs historically to treat patients for the specified condition.⁴⁵ Their theory was that episode-based payment would motivate the choice of lower cost treatment regimens which motivation did not exist in traditional Fee For Service (FFS) payment, and that by following clinical practice guidelines and pathways, outcomes would improve as well. The proposal was not adopted.

The next year, United Healthcare completed another pilot study with five physician groups in Georgia, which had begun in 2009 and continued through 2012, paying them a single, episode-based fee to treat their patients. The designers of the United program criticized Bach's earlier proposal on the grounds that while it attacked drug costs, it had no effect on other categories of cancer care which were significant.⁴⁶ For their commercially insured patients, chemotherapy drugs represented 24% of total care costs, inpatient and outpatient facility costs were 54% and physician services accounted for the 22% remainder. They approached the drug costs by using average sales price, adding a small care management fee, and the rest of the payment using FFS contracted rates. The results on the total costs of care was a reduction of fully 34%. But paradoxically, the pilot resulted in a 179% increased chemotherapy drug costs. Analysis of the results did not identify a clear reason for the reduction in overall costs. There was some speculation that because they knew their performance was being measured and it would be shared among participants, the oncologists changed their behavior to score well. The reviewers were unable to determine why the chemotherapy costs increased since there were four specific incentives to lower costs. The pilot was abandoned after 2012.

Until 2015 when Medicare introduced its Oncology Care Model, and shortly thereafter, there were a range of efforts reported in a number of surveys,⁴⁷ as well as stand alone press releases

⁴⁴ For a nice review of various approaches to oncology payment including the majority of approaches, set forth in a graph, see, Runyan, Banks and Bruni, "Current and Future Oncology Management in the United States," *J. of Mgd Care & Spec Pharmacy* (February 2019) pp. 272-281 <https://www.jmcp.org/doi/full/10.18553/jmcp.2019.25.2.272> (accessed 11-23-2019)

⁴⁵ Bach, Mirkin and Luke, "Episode-Based Payment for Cancer Care: A Proposed Pilot for Medicare," *HEALTH AFFAIRS*, (2011) PP 500-509

⁴⁶ Newcomer, et al., "Changing Physician Incentives for Affordable, Quality Cancer Care: Results of an Episode Payment Model," *Journal of Oncology Practice* (Sept 2014), <https://ascopubs.org/doi/full/10.1200/JOP.2014.001488> (accessed 11-10-2019)

⁴⁷ As the basis for the descriptions of various programs, unless there is a specific citation for the description all are taken from the following articles: Deloitte, "The evolution of oncology payment models: What can we learn from early experiments?" (October 2016); <https://www2.deloitte.com/content/dam/Deloitte/us/Documents/life-sciences-health-care/us-lshc-evolution-of-oncology-payment-models.pdf>; Margolis Center for Health Policy, DUKE, "Exploring approaches for value-based reimbursement of oncology therapies (Oct 2017) https://healthpolicy.duke.edu/sites/default/files/atoms/files/oncology_backgrounder_09_28_17.pdf; Robinson, "Value-Based Physician Payment in Oncology: Public and Private Insurer Initiatives" *Milbank Quarterly* (March 7, 2017) pp 184-203, <https://onlinelibrary.wiley.com/doi/abs/10.1111/1468-0009.12249>; and Saulet. Wister and Price, "Your guide to oncology payment reform pilots," *Advisory Board* (March 26, 2018) <https://www.advisory.com/research/oncology-roundtable/oncology-rounds/2018/03/payment-reform-pilots> (all accessed 11-10-2019)

from payors and providers announcing their new initiatives. The problem with FFS payment, apart from the drug cost issues noted above, was that there was no mechanism to pay physicians for the myriad services besides office visits or hospitalizations that are essential to cancer care including care planning, team-based care, after hours access to services to forestall emergency department visits, better planning and use of imaging services, palliative services and use of evidence-based treatment to match the patient's specific clinical profile. Five basic models of alternative payment have been used: (1) bundled and episode payment; (2) oncology specific accountable care organizations (ACOs); (3) medical homes; (4) clinical pathway adherence; and (5) bonus payments.

3.1 Bundled and Episode Payment

Some of these models are based on a simple flat rate. Some are paid prospectively. Some pay FFS during the course of treatment with a reconciliation of expenses at the conclusion of the bundle. United, again, this time with MD Anderson, launched in 2014 a bundled payment which was paid prospectively for head and neck cancers. Humana used bundled payment for 13 cancers with 21st Century which went bankrupt in 2017. Patients with bone metastases and prostate cancer got more evidence-based care under the model. Horizon with Regional Cancer Care Associates (RCCA) in NJ, using a third party affiliate of RCCA called Cancer Outcomes Tracking and Analysis (COTA), created far more sophisticated granular data focusing on cancer subtypes and molecular characteristics which is very difficult to do otherwise. Anthem Blue Cross of California with Valley Radiotherapy Associates launched a bundled payment model in May 2017 for breast cancer. Highmark, Allegheny Health Network and Johns Hopkins also focused on breast cancer in their bundled payment model.

Horizon Blue Cross and Blue Shield of New Jersey has used an episode payment model with Regional Cancer Care Associates, for treating breast and prostate cancer.⁴⁸ As of June 2019, with 370 cancer episodes completed, there was an average saving of \$250 per episode and total savings in 2017 of \$92,500. The American Society for Clinical Oncology (ASCO) has criticized bundled payment because it would motivate physicians to use lower cost drugs at the risk of sub-optimal care.⁴⁹

3.2 ACOs

Baptist Health of South Florida with the Florida Blues plan and Advanced Medical Specialists formed an oncology specific ACO which demonstrated savings of 2% of overall costs in its first year. Similarly, Moffit Medical Center with the Florida Blues plan also created an oncology specific ACO which produced reduction in readmissions, improved drug prescribing and increased conformity with clinical practice guidelines. For sure there are other such experiments elsewhere, as well.

⁴⁸ Personal communication, 7-11-2019 from Steven Peskin, MD.

⁴⁹ LaPointe, "Do Oncology Bundled Payments Promote Low-Value Drug Use?", (July 25, 2017), <https://revcycleintelligence.com/news/do-oncology-bundled-payments-promote-low-value-drug-use> accessed 11-11-2019)

3.3 Medical Homes

Oncology medical homes, like traditional Patient Centered Medical Homes are an approach to reorganizing care delivery rather than a revised payment model per se. The first Oncology Patient Centered Medical Home® (OPCMH)® recognized by NCQA as such was the medical practice Consultants in Medical Oncology and Hematology outside of Philadelphia. Their leader, John D. Sprandio MD, has been a long-standing client of mine and has spoken and written often of how writings of mine influenced his creation of his medical home.⁵⁰ The change in performance, even with no change in reimbursement to the practice was to lower emergency department visits by 51%, lower inpatient admissions by 68% and save \$1 million per physician per year for payors. The COME HOME model, launched by Barbara McAneny MD from New Mexico and sponsored by the Centers for Medicare and Medicaid Innovation, involved 7 practices. They lowered emergency department visits by 1% and 30 day readmissions by 3.5%. The program was later adopted by ASCO as a model⁵¹, but they abandoned it as well. Horizon Blue Cross in New Jersey has used a medical home model with Regional Cancer Care Associates (RCCA) for both commercial and Medicare Advantage patients.⁵² RCCA also has a medical home contract with Aetna.⁵³

Unlike medical home models with no payment support, in Michigan, Priority Health and Cancer and Hematology Centers of West Michigan initiated a medical home program with a per member per month care management fee which lowered costs \$550 per patient in the program along with lowered inpatient admissions and emergency department visits.⁵⁴

3.4 Pathways

Several programs around the country have paid physicians who submit data and register their patients, for adherence to guidelines, whether those of NCCN (most typically) or home grown guidelines that incorporate assessments of cost effectiveness. In 2015 Anthem's program for breast, non-small cell lung cancer and colon cancer paid \$350 per month for patients on

⁵⁰ Butcher, "Medical home concept comes to oncology," Oncology Times, Feb 25, 2011, <https://journals.lww.com/oncology-times/pages/articleviewer.aspx?year=2011&issue=02250&article=00008&type=Fulltext>; George, "Oncologist bringing medical home concept to cancer docs," June 15, 2011, <https://www.bizjournals.com/philadelphia/print-edition/2012/06/15/oncologist-bringing-medical-home-model.html>; Burling, "Delco oncologist makes the most of efficient care," Philadelphia Inquirer, Oct 12, 2013, https://www.inquirer.com/philly/health/cancer/20131013_Delco_oncologist_makes_the_most_of_efficient_care.html (all accessed 11-11-2019) The paper he cites as so influential is "Doing Well By Doing Good: Improving The Business Case for Quality", co-authored with James L Reinertsen, MD; https://www.gosfield.com/images/PDF/uft-a_White_Paper_060103.PDF (all accessed 11-29-2019)

⁵¹ "ASCO Launches COME HOME Initiative to Give Oncology Practices Concrete Path toward Alternative Payment Model," Press Release, November 1, 2016 <https://www.asco.org/about-asco/press-center/news-releases/asco-launches-come-home-initiative-give-oncology-practices> (accessed November 29, 2019)

⁵² Karp, "Value-Based Oncology", presentation for Physician Information and Education Resource," personal communication from Steven Peskin

⁵³ Press Release, October 2016, <https://www.regionalcancercare.org/news/regional-cancer-care-associates-aetna-form-oncology-medical-home/> (accessed 11-30-2019)

⁵⁴ Priority Health: Oncology Medical Home Puts Patient Outcomes First," Fierce Healthcare, Nov 18, 2011, <https://www.fiercehealthcare.com/healthcare/priority-health-oncology-medical-home-puts-patient-outcomes-first> (accessed 11-9-19)

chemotherapy where their physicians followed pathways. Blue Cross Blue Shield of North Carolina in April 2017 reported paying a higher rate to physicians for guidelines adherence. Wellpoint also launched a program in 2014 to pay \$350 per member per month for guideline adherence. As early as 2010, BlueCross Blue Shield of Michigan sponsored the development of guidelines by physicians and paid a higher rate for conformity with them and for prescribing more generic drugs. Texas Oncology and Aetna had a program for 590 Medicare Advantage patients where physician adherence to treatment pathways and quality metrics were evaluated along with hospitalizations and ER use. Over the 3 years of the program, the cumulative cost savings were \$3,033,248 with per patient savings of about \$1874.⁵⁵

3.5 Bonus Payments

ASCO proposed in 2015 a four tiered payment model⁵⁶ it called Patient Centered Oncology Payment (“PCOP”): (1) New Patient Treatment Planning (a \$750 payment for each patient); (2) Care Management During Treatment (a \$200 payment each month for each patient); (3) Care Management During Active Monitoring (a \$50 payment each month for each patient during treatment holidays and for up to six months following the end of treatment); and (4) Participation in Clinical Trials (a \$100 per month payment for each patient while treatment is underway and for six months afterward for trials in which practice support is not available. With scant evidence of its adoption, by 2017, a different but similar proposal by Innovative Oncology Business Solutions (“IOBS”), Inc., an affiliate of the New Mexico Oncology Group, which had initially spearheaded COME HOME, was submitted to the Physician-Focused Payment Model Technical Advisory Committee (PTAC). It was approved as MASON (Making Accountable Sustainable Oncology Networks)⁵⁷. There remains little evidence it has been adopted, either, although the National Cancer Care Alliance is working with IOBS on implementation.

Yet payors have entered into a variety of forms of bonus payments. Since 2016 a Blues plan in the west has paid a one time \$375 new patient care management fee, a fee of \$100 per member per month for each patient on chemotherapy and \$25 per member per month for post-chemotherapy active monitoring of patients and then, also, paid the ASCO PCOP suggested rates.⁵⁸

3.6 Challenges to Widespread Change

As we have seen, a wide variety of approaches have, at least initially, and on a small scale, produced improved care at lower costs. Whether these are the best potential results remains unknown; nor are the results necessarily comparable because of the diversity in

⁵⁵ “Texas Oncology, Aetna Collaborate to Improve Patient Care Through Clinical Pathways,” *Journal of Clinical Pathways* (March 22, 2018) <https://www.journalofclinicalpathways.com/news/texas-oncology-aetna-collaborate-improve-patient-care-through-clinical-pathways> (accessed 11-30-2019)

⁵⁶ ASCO, “Patient Centered Oncology Payment,” (May, 2015) <https://practice.asco.org/sites/default/files/drupalfiles/asco-patient-centered-oncology-payment.pdf> (accessed 11-11-2019)

⁵⁷ Firth, “PTAC OKs New Payment Model for Community Oncology,” (Dec 11, 2018) <https://www.medpagetoday.com/publichealthpolicy/medicare/76857> (accessed 11-11-19) The differences included an additional oncology payment, a different approach to setting prices and targets, among other design differences. Personal Communication, Barbara L. McAneny, M.D., December 24, 2019.

⁵⁸ Personal communication, documents subject to confidentiality and non-disclosure agreement.

the approaches. In fact, ASCO formally takes the position that physicians should have access to a variety of payment options.⁵⁹ Besides potential legal and regulatory issues, depending on how payments flow in a bundled payment arrangement, several other challenges to widespread adoption of change have been noted.⁶⁰ These include difficulty in the reliability of the models because they entail buy-in from multiple stakeholders: physicians, payers, providers, patients, pharmacy benefit managers (PBMs), employers and manufacturers. Scalability is the problem with how models can be replicated widely. Given the technical precision and personalized nature of cancer treatment and the challenge of developing sufficient data to prove viability of the approach, the development of models to date has been fairly idiosyncratic in the commercial payer arena.

There are a host of operational issues in developing and implementing alternative payment models, the first of them being the long-standing reliance of oncologists on the drug margins to support their practices. Not believing they will be kept whole, if not given additional revenues, they are reluctant to change to an unknown program which likely requires and is intended to motivate change in the actual processes to deliver care. Those who have succeeded with new models acknowledge the very different mindset a more efficient model demands⁶¹, given the complexity of delivering cancer care as distinct from replacing a knee or treating a myocardial infarction. But, what Medicare does in cancer care payment is far more of a driver of reform because of the fact that cancer is a disease of aging. Consequently, the Medicare model merits closer attention.

4. The Oncology Care Model (OCM)

In 2015, CMS launched a five year voluntary new payment model called the Oncology Care Model.⁶² The fundamental offering was a per-beneficiary-per-month additional payment of \$160 for the provision of enhanced services – the monthly enhanced oncology services (MEOS) payment; plus performance based payment (episode payment model - EPM). The designers claimed to have considered using a patient centered oncology medical home, an oncology-centered accountable care organization model or a clinical pathways adherence model. Ultimately, they settled on a blended model which combines patient coordination elements of a medical home with the payment incentives of a bundled payment model⁶³, although technically this is not a bundled payment model since it is only about paying physicians and not any of the

⁵⁹ “ASCO Urges Multiple Cancer-Focused Alternative Payment Models, Proposes Medicare Demonstration that Uses Evidence-based Oncology Clinical Pathways,” (November 28, 2017) <https://www.asco.org/advocacy-policy/asco-in-action/asco-urges-multiple-cancer-focused-alternative-payment-models> (accessed 11-11-2019)

⁶⁰ See DUKE, *supra* n. 47

⁶¹ See Sprandio, *supra* n.50.

⁶² For their own description of what they did and the challenges they faced, see Kline et al, “Design Challenges of an Episode-Based Payment Model in Oncology: The Centers for Medicare & Medicaid Services Oncology Care Model,” *Journal of Oncology Practice*, July 1, 2017) e632-e645; <https://ascopubs.org/doi/full/10.1200/JOP.2016.015834> (accessed 11-9-19)

⁶³ Kline et al, “Centers for Medicare and Medicaid Services: Using an Episode-Based Payment Model to Improve Oncology Care,” *Journal of Oncology Practice* (February 17, 2015)

other providers treating the patient for the episode.⁶⁴ CMS sought the participation of private payers as well to enhance the impact of the model. With regard to that participation they said,

“OCM is a multi-payer model that includes Medicare fee-for-service (OCM-FFS) as well as commercial payers working together to transform care for all patients living with cancer. Although there are differences between OCM-FFS and other payers in certain areas, such as specific payment amounts and episode definition, the approach to practice transformation is consistent across all payers in OCM. OCM payers will align their models with OCM-FFS in the following ways: provide payments for enhanced services and for performance; include patients receiving chemotherapy as a focus of the model; share data with participating practices; and align on a core quality measure set. CMS will provide opportunities for OCM payers to convene regularly throughout the model to share lessons learned on engaging in alternative payment model work that supports oncology practice transformation.”⁶⁵

4.1 The Model

The MEOS amount offered was calculated based on the estimated additional staffing required to provide the enhanced services which were expected to include the following: (1) provide and attest to 24 hour 7 day a week patient access to an appropriate clinician who has real-time access to the practice’s medical records. Remote access including telephone access can qualify. Nurses, non-physician practitioners and physicians are all permitted here. (2) They must attest to their intent to meaningfully use EHR technology certified by the Office of the National Coordinator They have to attest to Stage 1 by the end of the first performance year and to Stage 2 by the end of the third performance year. (3) They must utilize data for continuous quality improvement and must collect and report data regarding specified metrics. The CMS Innovation Center intended to provide them quarterly reports based on claims received, but the practices are also expected to generate their own data internally for improvement. (4) They are expected to provide the core functions of patient navigation as specified by the National Cancer Institute.⁶⁶ (5) They must document a care plan that contains the 13 components in the Institute of Medicine Care Management Plan⁶⁷, engaging patients in the development of the plan. The agreements

⁶⁴ In a true bundled payment model, multiple providers are at risk together. Here, only the physicians are at risk and for services provided by others. For a discussion of true bundled payments and the design issues associated with them see Gosfield, “[What's Fair In Bundled Payment Contracting?](https://www.managedcaremag.com/archives/2013/10/whats-fair-bundled-payment-contracting)” Managed Care, Oct. 2013; <https://www.managedcaremag.com/archives/2013/10/whats-fair-bundled-payment-contracting>; and Gosfield, “Bundled Payment: Avoiding Surprise packages”, HEALTH LAW HANDBOOK (2013 Ed), WestGroup a Thomson company, <https://www.gosfield.com/images/PDF/AGosfield.Bundled%20Payment.pdf>

⁶⁵ <https://www.cms.gov/newsroom/fact-sheets/oncology-care-model> (accessed 11-11-19)

⁶⁶ These include ten elements: 1. Coordinating appointments with providers to ensure timely delivery of diagnostic and treatment services; 2. Maintaining communication with patients, survivors, families and the healthcare providers to monitor patients’ satisfaction with the cancer care experience; 3. Ensuring that appropriate medical records are available at scheduled appointments; 4. Arranging language translation or interpretation services; 5. Facilitating financial support and helping with paperwork; 6. Arranging transportation and/or child/eldercare; 7. Facilitating linkages to follow-up services; 8. Community outreach; 9. Providing access to clinical trials; and 10. Building partnerships with local agencies and groups (e.g. referrals to other services and/or cancer survivor support groups). “National Cancer Institute Center to Reduce Cancer Health Disparities Patient Navigator Research Program.” Available at <http://www.cancer.gov/aboutnci/organization/crchd/disparities-research/pnpr>

⁶⁷ These are 1. Patient information (e.g. date of birth, medication list, and allergies); 2. Diagnosis, including specific tissue information, relevant bio markers, and stage; 3. Prognosis; 4. Treatment goals (curative, life-prolonging,

between the practice and CMS include more detail regarding more specific reporting. (6) They must treat patients with therapies consistent with nationally recognized clinical practice guidelines. If they deviate from those guidelines, they must document why. The MEOS payment is available for six months after a patient initiates chemotherapy, whether oral or infused, and regardless of whether he only gets the drugs for four months. Practices have to apply for the payment; it is not made automatically based on claims submission for drug administration. Beneficiaries who need additional chemotherapy are eligible to have their chemotherapy paid to the treating physician, in addition, with another MEOS payment.

The EPM through which physicians may get additional payment based on performance is a total cost of care model. This means that some acute events out of the oncologist's control are counted in measuring cost savings; and the calculation includes all the services the patient receives that are paid for by Parts A, B and D, which means chemotherapy drugs are included in the costs attributable to their budget. So, whether the patient goes to the emergency department for something utterly unrelated to the cancer care like a car accident, or sees three other physicians for a condition unrelated to oncology like brittle diabetes, all of those costs count against the treating oncologist's budget. In determining attribution of patients, CMS considered using an initiation of services model --which would pay the MEOS prospectively -- versus a plurality of services model --which would determine who provided the bulk of the services, so it would, of necessity, be retrospectively paid. Although the designers found that both methods produced the same results 81% of the time, they chose the plurality model on the theory that it was more likely to identify the physician group caring for the patient over time. Still further, acknowledging the complexities in the organizational arrangements of oncologists, the model requires any participating group to include in its participation for payment, all practitioners who furnish chemotherapy services at all locations at which such services are furnished. So, physicians who do not provide chemotherapy in their offices, but otherwise treat the patient and manage the chemotherapy at hospital locations where hospital clinicians may supervise, must include those additional clinicians in their costs of care as well.

Keeping in mind that CMS only gets claims data to make all these determinations, they were limited in how they could approach designing payment around practice expenditure variations, risk adjustment and benchmark episode prices. The discussion of how they approached these issues methodologically including regression based risk-adjustment

symptom control, palliative care); 5. Initial plan for treatment and proposed duration, including specific chemotherapy drug names, doses, and schedule as well as surgery and radiation therapy (if applicable); 6. Expected response to treatment; 7. Treatment benefits and harms, including common and rare toxicities and how to manage these toxicities, as well as short term and late effects of treatment; 8. Information on quality of life and a patient's likely experience with treatment; 9. Who will take responsibility for specific aspects of a patient's care (e.g. the cancer care team, the primary care/geriatrics care team, or other care teams); 10. Advanced cancer plans, including advanced directives and other legal documents; 11. Estimated total and out-of-pocket costs of cancer treatment; 12. A plan for addressing patient's psychosocial health needs, including psychological, vocational, disability, legal or financial concerns and their management; and 13. Survivorship plan, including a summary of treatment and information on recommended follow-up activities and surveillance as well as risk reduction and health promotion activities. Institute of Medicine, Report Levitt, Balogh, Nass and Ganz ed, DELIVERING HIGH QUALITY CANCER CARE: CHARTING A NEW COURSE FOR A SYSTEM IN CRISIS. (2013)

methodologies, while described in detail, is unfathomable to me (who has worked on developing two different payment models including an OCM v 2.0) and is likely utterly beyond the ken of most physicians. The fact that CMS only has claims data for staging of disease is a real impediment to meaningful payment, because claims for CPT codes do not reflect staging, nor do the diagnosis codes which must be included as well. CMS did develop an approach to accommodate new drugs with the hope that their approach would encourage cost effective drug use.

The initial performance-based payment was upside only, meaning only additional payments would be made and no return of monies or deductions (downside risk) would be made from the monies otherwise to be paid to the oncologists. Beginning in 2017, a participating practice could choose two-sided risk which qualifies as an Advanced Alternative Payment Model under CMS' separate Quality Payment Program initiatives. Taking two-sided risk, participants would be required to pay CMS if aggregate actual episode expenditures for their episodes in a performance period exceed the sum of the target prices for those episodes. Interestingly, although the MEOS was intended to facilitate change in care delivery and pay for the costs of those changes, and the results of change were also expected to change the costs associated with those changes permitting physicians to benefit from improved performance, there is no evidence that any of that has actually happened. As of the end of 2019, practices which had not received performance bonus payments had to accept downside risk or leave the model. Practices sought delay in making the decision from October 2019 to April 2020 in order to have more recent performance data available to them.⁶⁸

The design of the model has been criticized on a variety of bases⁶⁹. The bundles are actually measurement of costs incurred by providers other than the practice without affecting those providers financially. Because they turn in part on historical costs for the practice, the result is for a practice to end up competing against itself with diminishing returns over time if it, in fact, improves it's care delivery. The choice of six months as the episode for chemotherapy is arbitrary and reflects nothing of a clinical nature. Perhaps the most controversial aspect of the bundle is the inclusion of total costs of care to the patient, irrespective of whether the treating oncologist has any control over those costs and the inclusion of drugs in the payment. But the physicians have precious little control over the pricing of the drugs, (even in light of the buy and bill model) which makes little logical sense in a value-conscious environment. The theory is that by being at risk for drug costs, physicians will choose less expensive and generic drugs. Proponents of this position argue that 20%-30% of annual spending on off-label drugs represents enormous waste in the system, although others argue that evidence for this position is "sparse."⁷⁰

⁶⁸ LaPointe, "Practices Ask for Downside Risk Delay for Oncology Care Model", (June 3, 2019), RevIntelligence Cycle; <https://revcycleintelligence.com/news/practices-ask-for-downside-risk-delay-for-oncology-care-model>

⁶⁹ Thomas and Ward, "The Oncology Care Model: A Critique", ASCO Educational Book (October 29, 2018) e109-e114; https://www.researchgate.net/publication/303743350_The_Oncology_Care_Model_A_Critique (accessed 11-23-2019)

⁷⁰ Id.

4.2 Working Under The Model and Results

As of December 2016, 175 practices participated in OCM ranging in size from 1 oncologist to over 350.⁷¹ Ten commercial payers participated as well.⁷² The bulk of the OCM participants have been independent community-based oncology practices while 37 were hospital-affiliated or owned.⁷³ It is noted among commentators that hospital-based practices are protected from the otherwise penurious impact of drug costs because of the availability to them of the 340B program.⁷⁴

The results of the OCM have been decidedly mixed and somewhat tepid. Members of Premier's Bundled Payment Collaborative earned performance-based payments in the first two performance periods, out-performing their peers by 100% and 27% for those periods respectively.⁷⁵ But likely they started from a better baseline than their peers. It is reported that participants in the model have reordered their practices with same-day appointments, oncology-specific urgent care clinics, and telephonic triage and protocols to provide timely, evidence based care. The mandate to implement the NCI care changes has produced some alterations. These commentators observed, however, that on average, drug expenditures constitute 42.6% of total episode costs. Even with the novel therapies adjustment, the OCM methodology seems inadequate to be able to respond to the pace of change. They further criticized the fact that the MEOS payment is also included as a cost to the practice. The attribution process also came in for reproach because it is much harder to track a patient's initiation of oral therapy than in office administered infusion therapy.

A variety of practices report that despite transformation of care delivery they made no money. The oncologists at Lancaster General Medical Group in Pennsylvania, were paid bonuses on 6 out of 10 episodes, saved more than 4% off their baseline, but by June 2019 had made no money.⁷⁶ Still they changed significant aspects of their care delivery system including preparing to become a team using team science; becoming more lean; and using daily huddles among the staff. New Mexico Oncology Hematology Associates has a demographic profile where they treat poor people. They started from a baseline of being 40% under average for hospitalizations and emergency department admissions.⁷⁷ They also lost money because when they did real cost accounting with regard to what it took to

⁷¹ CMS, "Evaluation of the Oncology Care Model: Performance Period One",

<https://innovation.cms.gov/Files/reports/ocm-secondannualeval-pp1-fg.pdf>; accessed 11-23-2019

⁷² Aetna; Blue Cross Blue Shield of Michigan/Blue Care Network; BlueCross BlueShield of South Carolina; Cigna Life & Health Insurance Company; Health Care Services Corporation; Highmark, Inc.; Priority Health; SummaCare; The University of Arizona Health Plans; UPMC Health Plan, although the CMS website reports 14 participated

⁷³ Davidoff et al., "What is The Oncology Care Model, and Why Is The Evaluation Important?" *Health Affairs Blog* (February 14, 2019) <https://www.healthaffairs.org/doi/10.1377/hblog20190212.101448/full/> (accessed 11-23-2019)

⁷⁴ See n. 16 supra.

⁷⁵ Pittman, Rossi and Pini, "Three Benefits To The Oncology Care Model and Four Recommendations To Advance It," *Health Affairs Blog* (April 22, 2019), <https://www.healthaffairs.org/doi/10.1377/hblog20190417.733414/full/> (accessed 11-29-2019)

⁷⁶ Comments of Randall Oyer, MD at National ACO Summit X, Bundled Payment Summit IX and MACRA Summit IV, June 19, 2019

⁷⁷ Comments of Barbara McAneny, MD at National ACO Summit X, Bundled Payment Summit IX and MACRA Summit IV, June 19, 2019

deliver drugs, it was \$600 for each patient, but Medicare essentially was paying only \$300.

A company which supports 1000 oncologists working under the model found that 35-40% did better in Performance Period 4, but while only half the practices improved, half did worse, in part because when the target budgets were created, many of the new oral chemotherapies used today were not even on the market.⁷⁸ They lament the very long lag time in getting actionable data from CMS. They decry the absence of appropriate credit for staging and novel therapies. The key drivers of success turned on drug use, case mix, end of life treatment and use of generic drugs. Surprisingly, one of the other complaints turns on the difficulty practices have in identifying OCM episodes.⁷⁹ By June 2019, 20% of practices' overall effort was spent just in identifying OCM episodes because the MEOS payment has to be affirmatively claimed; it is not automatically paid by CMS when they receive an initial claim for chemotherapy. Some of the problem may also turn on the increased use of oral chemotherapies which are harder to track in terms of use than infusions provided in the medical office.

Other practices reported that the model required them to develop a host of changes: accurate tracking of the start and end of episodes, data management to report quality measures, patient safety steps that featured morning “safety huddles”, staff schedules based on patient needs, adverse event reporting, improved patient education and financial counseling and better pharmacy integration.⁸⁰ They improved their response times to phone calls, they embedded palliative care in their outpatient clinics, and have reduced their treatments in the last six months of of life.

As they confronted the decision regarding accepting downside risk, the Community Oncology Alliance (COA) which represents community-based independent oncology practices, criticized the risk adjustment and baseline pricing practices in OCM and called for other changes in the model as well:

- *Implement more sophisticated pricing models that allow for risk adjustment for high-risk patients and are more clinically motivated*
- *Add surgeries related to all cancer types to the surgery list so if patients undergo surgery for any type of cancer, the target price will reflect the increased complexity of their episode*

⁷⁸ Charles Saunders MD, podcast interview, “Dissecting OCM Performance Period 4 Results and Their Implications” Published Sept 24, 2019, <https://www.ajmc.com/managed-care-cast/dissecting-ocm-performance-period-4-results-and-their-implications> (accessed 11-23-2019)

⁷⁹ Saunders, “What are the latest results from Medicare’s Oncology Care Model?”, MedCity News (Jun 5, 2019) <https://medcitynews.com/2019/06/what-are-the-latest-results-from-medicare-ocm/> (accessed 11-23-2019)

⁸⁰ Report of Tennessee Oncology in Caffrey, “With the Oncology Care Model, “Everyone Has to Be Engaged,” including Patients, “ *American J of Managed Care* (April 12, 2018) <https://www.ajmc.com/newsroom/with-the-ocm-everyone-has-to-be-engaged-including-patients> (accessed 11-23-2019)

- *Exclude patients with certain disorders (e.g., hemophilia and Guillain-Barre syndrome) and high-utilization events from the OCM to prevent outliers beyond the oncologists' control*
- *Notify providers as quickly possible after an episode is triggered or attribute patients to an oncologist based on the triggering chemotherapy claim*
- *Release monthly, rather than quarterly reports, to help practices' manage patient costs*
- *Assign patients with the most resource-intensive cancer type using data from claims and staging*
- *Account for metastatic disease in pricing estimations⁸¹*

One consulting organization has estimated that more than half and as many as 70% of the practices participating in the OCM would owe CMS money if they accepted downside risk, and the better number reflects changes CMS has made to the way downside risk will be calculated.⁸² Groups which received the performance based bonus are in a better position to accept two-sided risk, which offers still additional money to those who succeed, but puts them at risk if they don't save money. Practices who achieved Performance Based Payments in the first three years of the program can stay in the upside only version, but the factors implicating the ability to earn those payments include, in large part the total cost of care measurement. One group reported that two patients with nursing home admissions for bed sores, generated \$100,000 in costs, when the oncologists were neither responsible for nor actually treating the patients for their diabetic conditions which led to the expenses.⁸³

[Data on Who Dropped Out and Who Stayed, look at fn 84]

5. *What's Next?*

It is indeed interesting to note that not a single approach to paying for value in cancer care has taken hold nationally. The medical home experiment was not met with very much payer enthusiasm.⁸⁴ At this writing, we will soon learn how many practices are willing to continue playing under the OCM. Various payers will, apparently, continue to experiment with approaches to spurring contained costs and improved outcomes for cancer patients, such as Humana, who in April of 2019, announced its fourth payment

⁸¹ LaPointe, "Practices Ask for Downside Risk Delay for Oncology Care Model", (June 3, 2019), RevIntelligence Cycle; <https://revcycleintelligence.com/news/practices-ask-for-downside-risk-delay-for-oncology-care-model>

⁸² Kane et al, "More than Half of All OCM Providers Could Owe CMS Money if Required to Join in 2-Sided Risk Model", AValaere (May 21, 2019) <https://avalere.com/press-releases/more-than-half-of-all-ocm-providers-could-owe-cms-money-if-required-to-join-in-2-sided-risk-model> (accessed 11-29-2019)

⁸³ Narozniak, "OCM Participants Consider Costs of 2-Sided Risk" OneLive (Nov 25, 2019), <https://www.onclive.com/web-exclusives/ocm-participants-consider-costs-of-2sided-risk> (Accessed 11-29-2019)

⁸⁴ Butcher, "Some Builders' Remorse: The Rise and Fall of The Oncology Medical Home," *Managed Care* (May 1, 2017) <https://www.managedcaremag.com/archives/2017/5/some-builders-remorse-rise-and-fall-oncology-medical-home> (accessed 11-29-2019)

model focused on specialty care⁸⁵. Their Oncology Model of Care program launched with at least twelve practices throughout the country. The groups are paid a care coordination fee along with analytics to support the providers.⁸⁶

5.1 CMS Following On

CMS itself is proposing a follow on program to the OCM that would include more private payers and hold practices more accountable for quality and costs of care. They are calling this the Oncology Care First (OCF) Model to start in January 2021. It would include financial incentives to reduce reliance on FFS care. As currently conceived, participating practices would receive a prospectively paid monthly payment for Medicare FFS beneficiaries with cancer or cancer-related diagnoses to cover evaluation and management services and a separate category of enhanced services, as well as drug administration services. Still the practices would be held accountable for the total cost of care for Medicare costs, including drugs whether paid for under Part B or D.⁸⁷ Instead of being triggered by chemotherapy claims, OCF would be based on the patient's diagnosis of cancer or cancer related treatment and receipt of an E & M service for that. The monthly population payment (MPP) is available for attributed beneficiaries. The performance based episode payment, though, would only be available for beneficiaries receiving chemotherapy (excluding hormonal therapy) for a cancer diagnosis.

The budget for the MPP is based on historical data. The enhanced services component is for 6 of the services which were previously required under the OCM, plus the implementation of electronic patient-reported outcomes (ePROs). The payment is based on a Management Component (enhanced services and E&Ms), and an Administration Component (drug administration services, E & M payments to hospital outpatient departments where applicable). But the prospective payments are to be made based on median historical expenditures trended forward. The Performance Based Payment (PBP) is based on total episode expenditures reconciled against a benchmark or target amount. That amount is based on historical episode payments, trended forward, risk adjusted and adjusted for participant-specific experience and use of new drugs. The target amount is a benchmark discounted to provide savings for Medicare. The episode is triggered by receipt of chemotherapy and it lasts, again, an arbitrary six months. One of the major issues for oncologists will be, as in OCM, whether CMS will take into account their need for payments that provide sufficient financial margins to sustain their practices. The acronym of the PROMETHEUS Payment® model trademark remains critical for any model to succeed simultaneously at improving care, lowering costs and sustaining

⁸⁵ Castellucci, "Humana launches oncology payment model", Modern Healthcare (April 16, 2019) <https://www.modernhealthcare.com/insurance/humana-launches-oncology-payment-model> (accessed 11-29-2019)

⁸⁶ "Humana Launches Oncology Model of Care Program to Improve the Patient Experience and Health Outcomes in Cancer Care," (April 16, 2019) <https://press.humana.com/press-release/current-releases/humana-launches-oncology-model-care-program-improve-patient-experienc> (accessed 11-29-2019)

⁸⁷ "Oncology Care First Model: Informal Request for information", (November 1, 2019) <https://innovation.cms.gov/Files/x/ocf-informalrfi.pdf> (accessed 11-29-2019)

medical practice: Provider payment Reform for Outcomes, Margins, Evidence, Transparency, Hassle-reduction, Excellence, Understandability and Sustainability.⁸⁸

5.2 Another Way

In light of CMS’s proposal of the OCF model. COA withdrew its proposal to modify OCM for a version 2.0. Not so for a group of analysts, including myself, who have proposed a different way of coming at the complexities of cancer care with a clinically relevant model that has the opportunity to save money and improve care. In “Redesigning the Oncology Care Model”⁸⁹, an approach was taken to problems in the OCM: the reporting requirements are burdensome; the episode categories are not intuitive to clinicians and are so restrictive in their definitions that they have thwarted much participation by commercial payers. The Workgroup defined five key principles for redesign: (1) focus on episodes with the most opportunity for care redesign; (2) base episode budgets on what guidelines call for; (3) create cost accountability for what providers can control; (4) overlap policy should ensure appropriate opportunity in each applicable model; and (5) model evaluation is critical. To be sure, clinical pathways have figured in performance measurement in prior programs (See 3.4 above), but they have not been used as the basis on which to construct a budget for an episode payment. They have impliedly been considered more recently as having a role to play in setting target payments to assure that care is based on evidence⁹⁰, but the Workgroup proposal appears to be unique.

- (1) The cancers with the highest incidence rate in Medicare as well as mortality rates are breast, lung, prostate and colorectal cancer. Focusing there will get better traction in terms of effecting change. The basis for treating these cancers should be well accepted clinical practice guidelines to define the episodes as well as the budgets associated with treatment.⁹¹
- (2) Existing pathways are intended to direct oncologists to a course of treatment that is cost-effective, most efficacious and least toxic. They are tailored to individual patient needs and they reflect the way physicians actually treat

⁸⁸ I am the author of this concept intended to give the PROMETHEUS Payment® a meaningful name.

⁸⁹ Bluhm, de Brantes, Emanuel, Gosfield, Kolodziej, Rutledge (December 16, 2019) https://assets.ctfassets.net/vb7spb305cu5/7C9u8s0u9IgNqJvkjqAtdU/e95ec0319d7feaae8631e210ad012645/_2019_12_06_Remedies_Resigning_the_Oncology__1_.pdf (accessed 12-16-2019)

⁹⁰ Kuntz, “How Clinical Pathways Can Support Cancer Center Growth, Care Quality and Cost Containment”, Journal of Clinical Pathways (April 2019) <https://www.journalofclinicalpathways.com/article/how-clinical-pathways-can-support-cancer-center-growth-care-quality-and-cost-containment> (accessed 11-30-2019)

⁹¹ These principles were also relevant to the creation of the PROMETHEUS Payment Model in which I participated (see, Gosfield, “Making PROMETHEUS Payment Rates Real: Ya’ Gotta Start Somewhere,” (June 2008) <https://www.gosfield.com/images/PDF/MakingItReal-Final.pdf>; Gosfield, “PROMETHEUS Payment: Getting Beyond P4P”, Group Practice Journal (October 2006) <https://www.gosfield.com/images/PDF/106519GroupPracJour.pdf>; (accessed 11-29-2019) as well as the five fundamental principles set forth in Gosfield and Reinertsent, “Doing Well By Doing Good: Enhancing the Business Case for Quality,”: (1) standardize to the science as much as possible; (2) simplify processes; (3) make systems clinically relevant, especially payment systems; (4) fix accountability at the locus of control; and (5) engage with patients. https://www.uft-a.com/PDF/uft-a_White_Paper_060103.PDF (all accessed 11-29-2019)

patients. The National Comprehensive Cancer Network (NCCN) guidelines are widely accepted and could serve this purpose.

- (3) Clinicians should be accountable for their management of patients (technical risk) but not for either actuarial risk (the incidence of disease in the treated population) or risk of total costs of care. That said, physicians can be held accountable for prescribing effectively, but they ought not be held accountable for drug pricing. The discounts the manufacturers offer there, should be made available to Medicare.
- (4) Where Medicare uses payment models that relate to cancer care, such as the radiation therapy model⁹² these models will have to co-exist side by side. The radiation therapy model should be taken into account in assessing budgets and payment to physicians, without penalizing them for the expense associated with Medicare's payment to radiation therapists apart from the oncologists.
- (5) Evaluation of the model is critical. Although there was some disagreement among the Workgroup participants, in the last analysis the decision was made to recommend that some portion of the implementation of this model should be mandatory, while still offering the opportunity to participate to others who would volunteer to do so.⁹³

To do this work is not easy. One of the major problems with the CMS approach to these very complex challenges is the promulgation of a relatively simplistic model which accommodates the needs of a bureaucracy to implement easily. CMS should call on experts to assist in designing episodes and the rules for their triggering, breaking, concluding and attribution. The OCF appears to have made some minor progress. But the notion of paying for enhanced services without reference to the clinical relevance of them does not provide a model with much reliability in terms of what it will produce. To use clinicians, to analyze, literally, which services are necessary to produce what clinical practice guidelines or pathways call for is a better way to design a budget. Clinicians who can produce the results the guidelines claim for themselves by using more efficient

⁹² CMS, "Proposed Radiation Therapy Model" (July 2019) <https://www.cms.gov/newsroom/fact-sheets/proposed-radiation-oncology-ro-model>

⁹³ de Brantes, Bluhm, Gosfield, Kolodziej, Rutledge, "Redesigning Oncology Care: A Look at CMS' Proposed Oncology First Model" Health Affairs Blog, (Dec 16, 2019) <https://www.healthaffairs.org/doi/10.1377/hblog20191212.374702/full/> Another separate proposal has been offered by the Miller, Center for Health Care Quality & Payment Reform, "A Better Way To Pay For Cancer Care" (Dec. 2019) http://www.chqpr.org/downloads/Patient-Centered_Cancer_Care_Payment.pdf After criticizing OCM, as well as OCF, this report suggests adding new HCPCS or CPT codes for diagnosis and treatment planning, palliative care, ongoing care management and more with penalties to be imposed for failure to follow guidelines, high rates of ED visits and hospital stays for complications and for failure to deliver high quality services. The penalties would be imposed based on yet additional reporting by the practice regarding its adherence to guidelines and for the other penalties, by reducing the payment rate to practices based on their rates of inappropriate care. Although the report acknowledges that to operationalize the recommendations will require change at CMS, in my view, these proposals are unrealistic.

techniques deserve to make the money that would be reflected in the redesigned payment model.

6. *Legal Issues*

There has been scant discussion of legal issues in this presentation because at its core, the payment models will be captured in what has traditionally been called a managed care contract. These have been around for years. There are provisions in them that are immutable, including beneficiary hold harmless provisions, requirements of medical necessity for coverage of services, 24/7 physician coverage of patients, obligations to adhere to the plan's utilization review, quality assurance, credentialing and appeals systems. Record-keeping requirements, confidentiality both of rates and business methods of the plan, standardized claims submission and subscriber grievance systems are also typically addressed. Maintaining credentials and professional liability insurance, and standard contract boilerplate provisions are always seen.⁹⁴

Others are changing. Examples include whether the physician is participating for all programs of the payer or only those specifically addressed in exhibits, Some increasingly address the use of ancillary personnel, but many are silent on whether their services are included. Termination clauses may vary in terms of the length of notice, whether termination may only be made by the physician at the conclusion of the then current term, whether the physician may otherwise terminate without cause. Amendments clauses also may vary: some state that only mutually agreeable amendments will be legitimate; others allow for unilateral amendment by the plan to meet regulatory needs; still others permit a unilateral proposed amendment by the plan the rejection of which permits the agreement to proceed as it was; others say a rejection of a unilateral amendment is itself a terminating act; still others provide that if the physician accepts any payment after the amendment is proposed, that constitutes acceptance of the amendment.

Another range of provisions has emerged in light of the dynamism in the market where plans seek the participation of physicians. Physicians may be required to notify the plan of any merger or acquisition of other practices; and some agreements explicitly preclude the availability of negotiated rates to extend to such merged entities or even where there has been a significant change of control. Some require the physicians to notify the plan if they are going to introduce any new ancillary services. Some still include anti-disparagement clauses tempered by the explicit statement that physicians are permitted to discuss all treatment options with the payment.

As new payer contracts incorporate new payment models, the way those models are described and most importantly the data which will determine if performance measures have been met, are critical aspects of these documents. Challenging data-based determinations also ought to be addressed in the document. In addition, it may well be that the primary relationship establishing the payment is with a network or an ACO and

⁹⁴ For a deeper consideration of these issues see Gosfield, "The modern payer contract", *Dermatology World*, (November 2016) <https://www.gosfield.com/images/PDF/DermWorld.TheModernPayerContract.111816.pdf> (accessed 11-30-2019)

not the payer directly.⁹⁵ Then there are the contractual issues about establishing the rules of the game in any new payment model. These are typically handled as amendments to commercial or Medicare Advantage agreements. For Medicare FFS, there will be a contract as there is for OCM that states the rules of the game. The role for lawyers is to make sure that bedrock principles are in the contract, but that flexibility exists as the model unfolds to accommodate a newly defined reality.

Conclusion

There is, today, no single paradigm for paying for cancer care. The treatment of cancer is complex; and payment models need to embrace that complexity in a way that is meaningful to clinicians and patients. The payment for infrastructure improvement has proven only mildly effective. The implications of finding the right way to pay for cancer care will only increase as the population continues to age. This challenge is one that attorneys representing physicians will have to address with their clients in more innovative ways than has been the case to date.

⁹⁵ See, Gosfield, "[Avoiding Food Fights: The Value of Good Drafting to ACO Physician Participants](https://www.gosfield.com/images/PDF/PhysOrg.Avoiding%20Food%20Fights.June%202012.pdf)", AHLA Physician Practice Group (June 2012) pp. 10-11 <https://www.gosfield.com/images/PDF/PhysOrg.Avoiding%20Food%20Fights.June%202012.pdf> (accessed 11-30-2019)