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The Potential Impact of the New Accountable Care Organization Regulations on the Pharmaceutical and Medical Device Industries

In early April, the Center for Medicare and Medicaid Services (CMS) issued proposed implementing regulations as required by Section 3022 of the Affordable Care Act (the Act),[1] concerning so-called "Accountable Care Organizations." While much of the initial commentary has summarized the key provisions in the CMS proposal, this client alert analyzes how the Accountable Care Organization (ACO) rules are likely to impact pharmaceutical and medical device companies. In our view, these regulations, by virtue of their incentive structures, will push health care professionals and institutional providers who join together into an ACO to do two things that will impact such companies: (1) defer elective and costly medical procedures; and (2) choose the least costly alternative when treatment alternatives present.[2]

Top Line Summary

- The creation of Accountable Care Organizations will create powerful new financial incentives for health care providers and suppliers, which are likely to impact the cost and quality of health care for ACO beneficiaries.
- While the new incentives may drive changes that improve quality and reduce costs in some areas, they also create incentives for cost-shifting to entities outside the ACOs (like pharmaceutical and medical device makers) and are likely to raise barriers to patient access to high-quality but costly therapies and technologies. The safeguards in the proposed rule, particularly the quality standards, are both complex and subjective, and it is far from clear that such safeguards will ensure beneficiaries receive high-quality care.
- Pharmaceutical and device makers need to analyze and understand the likely impact of the proposed ACO rules and engage policymakers and others to ensure the promise of higher quality and more effective health care becomes a reality.

Overview

Section 3022 of the Act establishes a "Medicare shared savings program" through which a group of "providers of services and suppliers" can organize into a legal entity that establishes processes that seek to provide high quality of care through the promotion of "evidence-based medicine and patient engagement" to at least 5,000 program beneficiaries at a lower cost, which will be achieved through more effective management of the patient's overall health care needs. The Medicare program then will share some portion of the savings with the ACO members. Section 3022 provides few details on how to achieve this goal; the new proposed regulations are CMS's initial effort to structure the ACO program.

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1 On March 23, 2010, the Patient Protection and Affordable Care Act (Pub. L. 111–148) was enacted. Following the enactment of Public Law 111–148, the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152) (enacted on March 30, 2010) amended certain provisions of Public Law 111–148. These public laws are collectively known as the Affordable Care Act.

2 For an analysis of the proposed waivers of fraud/abuse laws for ACOs under the Medicare Shared savings program, see "Accountable Care Organizations – Fraud/Abuse Waiver Proposals May Have Major Impact on Providers, Suppliers and Others" at http://www.skadden.com/newsletters/Accountable_Care_Organizations_Fraud_Abuse_Waiver_Proposals.pdf.

Four core features of the statute, each of which will significantly impact the efficacy and operation of the program and the incentives created for those who will be in control of ACOs, are as follows:

- Even while a member of an ACO, a provider will be paid for the care she is providing to each patient she treats, "under the original Medicare fee-for-service program under parts A and B in the same manner as they would otherwise be made." 42 U.S.C. § 1899(d)(1)(A). Thus, the provider will provide care, and be paid, as she is presently paid throughout the year. If the ACO saves money, CMS will make a payment to the ACO, and the ACO, through its governance structure, will make a payment to its participants.
- There is no provision in the statute (or in the regulations) for CMS payment for the costs of ACO organization or operation. Thus, providers envisioning joining together in an ACO must anticipate that the ACO's ability to generate savings by reducing the cost of the care provided to the beneficiaries under its supervision will exceed the costs of implementing and operating the ACO.
- The statute does not limit in any way a beneficiary's freedom of choice among providers. A beneficiary, unhappy with the care provided by or through his primary care physician, can choose to get that care elsewhere or to seek a second opinion on a choice of treatment options. Thus, ACOs, while held accountable for all of the costs of the Medicare Part A and Part B care provided to a beneficiary assigned to that ACO, cannot control the care that the beneficiary seeks outside the ACO.
- The statute imposes no penalties on providers who do not participate in an ACO.

An individual provider only will have an interest in joining an ACO if the following is true:

Fee-for-service payments received for care provided to program beneficiaries, as controlled and limited by the governance processes implemented by the ACO	**+**	**Savings share from money returned to ACO by Medicare as generated by reducing services**	**–**	**Cost share to provider of operations of the ACO**	**>**	**Fee-for-service payments the provider could earn for services provided without constraints imposed by an ACO**

The details of the structure and payment mechanisms established by the proposed regulations, which we believe are relevant to companies in the pharmaceutical and medical device industries, are as follows:

ACO membership. The proposed regulations appear to exclude drug and device manufacturers from membership in an ACO. This means that drug and device companies that provide items critical to the care received by patients served by the ACO cannot receive a share of any savings generated through the operations of the ACO that limit the provision of care to the beneficiaries.

Membership in an ACO is limited to nine categories of participants: (1) octors of medicine or osteopathy; (2) physician assistants; (3) nurse practitioners; (4) clinical nurse specialists; (5) networks of the professionals specified in (1) through (4), and partnerships or joint ventures between hospitals and the professionals specified in (1) through (4); (6) hospitals that employ the professionals specified in

(1) through (4); (7) certain types of critical access hospitals; (8) providers, as defined in 42 CFR § 400.202; and (9) suppliers, as defined in Section 400.202, "that bill for items and services [furnished] to Medicare beneficiaries under a Medicare billing number assigned to the [Taxpayer Identification Number] of an ACO."

Pharmaceutical and medical device companies do not fall within the definitions of categories (1) through (8), leaving only category (9). The term "supplier," as defined in Section 400.202, is similar to the general definition under Medicare and is limited to: "a physician or other practitioner, or an entity other than a provider, that furnishes health care services under Medicare." While the term "services" is defined to include "drugs and biologicals" as well as "items," "appliances" and "equipment" (but not "medical devices"), the proposed regulations limit suppliers to those who "bill for items and services [furnished] to Medicare beneficiaries under a Medicare billing number." This clause would appear to preclude all pharmaceutical and device manufacturers from membership in an ACO.

In addition, Medicare Part D plans also may not be ACO participants.

Calculation of ACO savings. While the formula is complicated and there are alternative means for determining and sharing savings, the relevant aspects, as drug and device companies are concerned, are as follows:

- Medicare will assign beneficiaries to an ACO by determining all primary care services provided by primary care physicians for a beneficiary for the relevant year. If a member of the ACO is the doctor who provided "a plurality" of the primary care services, then the beneficiary is assigned to that ACO, and all of the costs of the Medicare Part A and Part B care provided to that beneficiary become a part of the ACO's costs for that year. So, if a patient has an emergency hospitalization for treatment for septicemia while on vacation in Florida during a two week period in the year, but had received primary care from the same primary care physician all year at home in Minnesota, all of the patient's costs, including the $35,000 DRG[3] payment to the hospital providing the Part A care for the septicemia[4] and all related Part B charges for that hospitalization, will be assessed to the ACO in which the primary care physician is a member.[5] Because the ACO will not be able to control a patient's choice of treatment options, the ACO will be responsible for charges for treatment over which it cannot exercise control. This will increase pressure on the ACO to control those costs over which its participants can assert control.
- Medicare will establish, using "the per capita Parts A and B fee-for-service expenditures for beneficiaries that would have been assigned to the ACO in each of the[] 3 prior years," a fixed benchmark "that is adjusted for overall growth and beneficiary characteristics." This benchmark will be updated annually.

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3 A "DRG" is a "diagnostic related grouping" and is a mechanism used by Medicare Part A to pay for hospitalizations. Broadly speaking, each hospitalization is classified into a DRG, for which the hospitals receive a lump-sum payment, without regard to the actual cost of performing the procedure for the particular patient. The hospital's actual costs are reported to CMS via annual cost reports, and that information, as collected from all hospitals, is used to set and adjust DRG rates. The system is designed to encourage efficiency and cost management.

4 Treatment of septicemia falls within DRG 870; the average cost in FY 2009 for one procedure was $35,921.

5 To "minimize variation from catastrophically large claims" CMS will truncate claims at the 99th percentile. In practice that means that if 99% of patients have a Part A and Part B per capita cost between $20,000 and $250,000," CMS only will exclude the costs for patients that are in excess of the $250,000 figure.

Note that the benchmark will **not** include charges associated with the beneficiary through Medicare Part D. This means that drugs paid for as injectables through Part B, or as a part of the cost basis of a DRG under Part A, will be included in the benchmark for the ACO, but that drugs prescribed to and paid for by the beneficiary through a Part D plan (or as an out of pocket expense) will not be included.

Given the short period involved (three years), and the calculation and payment of savings at the end of each calendar year, all participants within the ACO will operate with a short term view and accordingly with short term motivations.

- To qualify for any shared savings, the ACO must meet a minimum shared savings percentage.[6] For an ACO with "control" over the services provided to 10,000 Medicare program beneficiaries, the savings that can be achieved require minimum savings of at least the following:

  - Two-sided: a share in savings in excess of 2%
  - One-sided: a share in savings in excess of 3%

  ACO's must share in cost increases above 102% of the benchmark (subject to certain maximums). Thus, if the ACO's benchmark is $100, and it has agreed to share losses, it must achieve a cost reduction of more than $2 *plus the costs of ACO operation,* in order to generate any savings for its participants. And, those participants only will see a net benefit to ACO participation if the savings net of the costs of ACO operations, when added to their reduced fee-for-service earnings, are higher than what they could earn were they not a participant in the ACO.

  If costs rise above $102, the ACO will have to repay monies to the Medicare program (through a hold-back from the paid savings).

Quality standards for ACOs. The Act directs the secretary to establish quality standards ACOs must meet to qualify for shared savings payments. While the Act specifies a number of measures the secretary should consider (such as clinical processes and outcomes, patient and where practicable caregiver experience of care, and utilization), the statute gives the secretary broad authority to establish quality metrics and reporting requirements. The secretary has exercised this broad discretion by identifying 65 separate quality measures (described in 20 pages of the 127-page rule as it appears in the Federal Register) to be used in assessing ACO quality and performance. The quality metrics are complex and, in some instances, highly subjective, and it is far from certain that these safeguards will be sufficient to prevent inappropriate cost-shifting to entities outside the ACOs and/or the delay or denial of necessary and appropriate but high-cost therapies and technologies. What is likely is that compliance with these standards (as well as demonstrating to CMS compliance with these standards) will increase the costs of ACO operation.

ACO Operations in Practice

The theory behind ACOs is that the core participants in the ACO with control over its management — physicians and hospitals, for the most part — will have a shared interest in controlling, and the

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6 The regulations establish two models: the "two-sided" model in which the ACO agrees to share in losses each year of the three year contract period, and the "one-sided" model, in which the ACO agrees to share in losses only in the third year. The savings percentages vary depending on the number of beneficiaries that are assigned to the ACO.

ability to control, the delivery of care to the program beneficiary throughout the year and, through coordination of the care provided, will be able to provide all needed care at lower charges to Medicare.

Note that while it is in society's interest to reduce health care expenses overall, management of an ACO, in order to reap shared savings from the Medicare program, cannot simply reduce costs by imposing an across-the-board cut in excess of 2%, as that will result in a net decrease in fee-for-service billings for all ACO participants. Given the absence of a Medicare imposed penalty on a provider for failure to join an ACO, rational providers would refuse to join, or drop out of, an ACO implementing such a strategy. One can expect, within a rational ACO, a struggle over *which ACO participants will suffer a net loss of income.* One outlet for that power struggle that benefits all ACO members is a shifting of the pain of savings to suppliers to the ACO who cannot benefit from any shared savings. A second outlet is a shifting of the financial pain to those ACO members whose practices provide services to the fewest beneficiaries but contribute the most to the ACO's Medicare charges.

There are several classic mechanisms that an ACO can employ to control the cost of covered Medicare charges per beneficiary; we examine each in turn.

Reducing the cost of providing the care. While this is the classic response employed by a business trying to achieve an overall cost reduction, in the short run this mechanism will provide no opportunity to the ACO. The Medicare shared savings mechanism provides no incentive for the hospital or physician participants to reduce their own costs in order to benefit the ACO, as the ACO's performance benchmark is predicated on Medicare payments to the ACO. While cost control in a hospital can result in some downward incremental movement in the DRG payment rates, those changes will not be swift or sufficient to materially affect costs. In addition, the reduced charges or costs will become a part of the new benchmark against which future years will be measured; this in fact will act as an economic disincentive for the ACO participants to reduce charges: As the benchmark gets pushed down, it will become increasingly difficult to wring additional cost savings from suppliers of products, including drugs and devices. Costs savings, it must be assumed, will continue to benefit only each ACO participant and not the ACO.

Increase the volume of beneficiaries per ACO participant. Another mechanism by which an ACO could increase its participants' income is by steps designed to increase the volume of patients serviced by each member of the ACO while reducing the services per beneficiary. If an ACO can capture a greater percentage of the marketplace without increasing its participants, then each participant may earn more by seeing an increase in his/her/its volume of fee-for-service billings. Reductions in fees-for-services provided to any one beneficiary will be masked by the overall increase in fees. While there may be situations where participants flock in a particular marketplace to a dominant ACO, the antitrust protections built into the regulations make this form of market dominance unlikely, and the achievement of additional income for the single ACO participant unlikely.

Selection of program beneficiaries who are at lower risk for needing expensive care. While this incentive exists, the regulations expressly prohibit such conduct, and it can be expected by ACO participants that CMS will carefully police efforts by ACOs to preclude primary care physician treatment for expensive beneficiaries.

Reducing the number of services provided. This mechanism will be a significant tool for the ACO. In order to achieve cost savings, ACO management will undertake steps to reduce the number of services provided to the program beneficiary by, for example, reducing the length of hospital stays,

permitting fewer doctor visits or increasing the barriers to the prescription of durable medical equipment (so that less equipment is provided).

Changing the nature of the services provided. This also will be a significant tool and raises serious concerns for manufacturers. It can be expected that ACO management will encourage (or pressure) physicians to choose the least costly medically efficacious treatment alternative. In making this calculus — which treatment option is less expensive — the comparison will not be in absolute terms (which treatment option is the least expensive overall) but rather which treatment option adds the lowest additional cost to the ACO's aggregate Part A and Part B charges for all patients included in its beneficiary population because one of its ACO participants is the primary care physician for that program beneficiary. Some examples:

- Choosing a drug treatment regimen for a particular patient malady that is covered by Part D, as opposed to a treatment regimen that will contribute to Part A and Part B charges for the patient.
- Choosing a non-surgical alternative over a surgical alternative.
- Choosing a surgical alternative that can be performed on an out-patient basis versus an alternative that can be performed on an in-patient basis.
- Requiring use of the least expensive of treatment alternatives for the same procedure (*e.g.*, use of the least expensive equally efficacious injectable drug).
- Choosing a one-time surgical alternative to a long term, and ultimately more costly, injectable drug treatment plan.

Deferring non-emergency treatment into the next calendar year. The ACO savings mechanism financially incents ACO participants and management to defer expensive, non-emergency treatments. It will be a simple reality within an ACO that an ACO's management will push ACO participants to defer, toward the end of the year, all elective or non-emergency procedures into the next calendar year. It can be expected that rational ACO management and participants will monitor the expenses of the ACO against the benchmark, and as the benchmark is approached internal "resistance" to expensive procedures will increase. Examples include:

- The ACO may defer a patient's hip replacement from November to February.
- The ACO may defer, for a patient who has suffered a mild heart attack late in a calendar year, implantation of a stent or performance of CABG until after the first of a year while the patient stabilizes.
- A person suffering from chronic back pain who is a candidate for a spinal fusion may have his procedure deferred from November to March.

Controlling ACO Expenditures and the Effect on Drug and Device Companies

Controlling Part A and Part B expenses will present different challenges for the management of an ACO. There will be an uneasy tension within an ACO as each participant will want to maximize his or her or its own fee-for-service billings while hoping that the ACO will achieve cost savings by reducing Part A and Part B billings to CMS through mechanisms that do not affect the participant's own Part A or Part B billings. Thus, hospitals will want to see the ACO achieve reductions in beneficiary Medicare charges

other than in the Part A arena; doctors will not want to see their own fee-for-service billings reduced, and will push that the cost savings are achieved on the Part A side or in the Part B payments to suppliers.

Part A: Savings by reducing elective surgeries and psychiatric admissions. Total in-patient Part A payments in FY 2009 were $126,336,514,673.[7] The chart below reflects, for that fiscal year, the top 22 DRGs[8] for the Medicare program. The monies spent in these 22 DRGs, out of more than 500 total DRGs, accounted for 34% of the total monies spent, and 25% of the total number of discharges. If effective charge reduction can be achieved by an ACO, it will be in one or more of these DRGs.

DRG	Medicare Reimbursement	Discharges	Cost per Discharge	Description
470	$4,701,121,727	506,568	$9,280	Major joint replacement or reattachment of lower extremity w/o MCC[9]
945	4,583,293,530	308,854	14,839	Rehabilitation w CC[10]/MCC
871	3,521,707,189	340,906	10,330	Septicemia or severe sepsis w/o MV[11] 96+ hours w MCC
885	3,168,878,452	451,881	7,012	Psychoses
3	2,947,783,492	27,584	106,865	ECMO[12] or trach w MV 96+ hrs or PDX[13] exc face, mouth and neck w maj OR
207	2,307,973,034	60,505	38,466	Respiratory system diagnosis w ventilator support 96+ hours
291	2,218,257,606	284,422	7,810	Heart failure and shock w MCC
4	1,808,657,694	27,636	66,987	Trach w MV 96+ hrs or PDX exc face, mouth and neck w maj OR
329	1,757,141,140	62,107	28,292	Major small and large bowel procedures w MCC
853	1,634,014,604	51,252	31,881	Infectious and parasitic diseases w OR procedure w MCC
247	1,608,430,878	176,508	9,138	Perc cardiovasc proc w drug-eluting stent w/o MCC
460	1,351,955,247	74,618	18,118	Spinal fusion except cervical w/o MCC
190	1,250,485,932	188,382	6,651	Chronic obstructive pulmonary disease w MCC
193	1,236,108,514	163,018	7,583	Simple pneumonia and pleurisy w MCC
292	1,215,164,354	244,626	4,980	Heart failure and shock w CC
194	1,185,820,512	236,739	5,024	Simple pneumonia and pleurisy w CC
870	1,154,342,555	32,135	35,921	Septicemia or severe sepsis w MV 96+ hours

(continued on next page)

7 All data in this alert comes from either https://www.cms.gov/MedicareMedicaidStatSupp/09_2010.asp#TopOfPage, or http://www.cms.gov/MedicareFeeforSvcPartsAB/.

8 The top 22 DRGs are those for which the Medicare program spent more than $1 billion.

9 Major complications and comorbidities.

10 Complications and comorbidities.

11 Mechanical ventilation.

12 Extra corporate membrane operation.

13 Primary diagnosis.

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208	1,154,132,722	94,099	12,278	Respiratory system diagnosis w ventilator support <96 hours
682	1,144,269,606	122,584	9,314	Renal failure w MCC
177	1,139,127,518	96,620	11,865	Respiratory infections and inflammations w MCC
189	1,074,551,517	124,128	8,665	Pulmonary edema and respiratory failure
981	1,018,175,569	34,910	29,165	Extensive OR procedure unrelated to principal diagnosis w MCC
T:	**43,181,393,392**	**3,710,082**		

In 2009, there were 46,489,141 Medicare program beneficiaries. An ACO with 10,000 program beneficiaries within its control can expect to have the following number of each of these procedures:

DRG Number	Rate[14]	Expected Number of Procedures[15]	Annual Cost to ACO
470	.011	109	$1,011,193
945	.0066	66	979,374
871	.007	70	723,100
885	.0097	97	680,164
3	.00059	6	641,190
207	.0008	8	307,728
291	.0061	61	476,410
4	.00059	6	401,922
329	.0013	13	367,796
853	.0011	11	350,961
247	.0038	38	347,244
460	.0016	16	289,888
190	.0041	41	272,691
193	.0035	35	265,405
292	.0053	53	263,940
194	.0051	51	256,224
870	.00069	7	251,447
208	.0020	20	245,560
682	.0026	26	242,164
177	.0021	21	249,165
189	.0027	27	233,955
981	.00075	8	233,320
T:		**1,781**	**$9,090,841**

In order to wring at least a 2% savings from this $9,090,841 expenditure, ACO management will have to reduce the number of procedures charged to the Medicare program. Management will not in the short run be able to control emergency admissions. It can be presumed that over the long term, as the ACO imple-

14 Calculated by dividing the number of procedures in 2009 by the number of program beneficiaries.

15 Rounded to the nearest whole number.

ments care measures that improve the overall health of each beneficiary, emergency admissions will drop; that will not benefit, nor act as an incentive for, ACOs in the short term. Given the three year measuring period proposed by CMS, it must be assumed that in every period, short term motives will prevail.

While broad generalizations are not perfect, DRGs 470, 945, 885 and 460 do not generally involve only emergency admissions, while the remaining DRGs in the top 22 generally involve emergency admissions.[16] DRG 470, the most expensive DRG, for example, covers hip replacement surgeries, many of which are non-emergency procedures for Medicare Program beneficiaries. Because DRG 460 (spinal fusion) involves only 16 admissions for our 10,000-member ACO, it presents little or no real opportunity for cost management (reducing admissions by two, or more than 10%), would save the ACO only $36,000 on its Part A allocation, or less than 0.4% of the total savings needed). Rational ACO management, evaluating the numbers listed above and consistent with the inability to control in the short run emergency admissions, will impose controls designed to drive down the number of elective or non-emergency in-patient admissions in DRGs 470, 945 and 885.

To achieve an overall 2% cost reduction, and thus to meet the minimum benchmark required to gain any shared savings from CMS, the ACO must eliminate $181,816 in in-patient Part A charges (assuming a similar 2% reduction in all Part B charges). If this reduction is shared proportionately by these three DRGs, that means the ACO must reduce the non-emergency major joint replacements by eight (or just over 7%), the non-emergency hospitalizations for rehabilitation by three, and the non-emergency hospitalizations for treatment of psychoses by nine.

While these numbers are rough, we believe that medical device companies can expect to see a drop in demand for devices used in elective joint replacement surgery by more than 5% in the Medicare population served by ACOs, if the proposed regulations are implemented without change. Pharmaceutical companies that supply drugs used in in-patient psychoses hospitalizations can expect to see a similar greater than 5% drop in demand.

Part B: Savings by reducing injectables. Part B presents a slightly more complicated picture for ACO management.

Total Part B expenditures for physicians and suppliers for FY 2009 were $91.4 billion. Narrowing this total to payments by DRG is complicated. Within this total, payments to internal medicine physicians accounted for $8.59 billion; payments to orthopedic surgeons was just $2.7 billion. Payments of $6.1 billion were made to anesthesiologists, some portion of which covered their attendance at procedures billed under DRG 470.

Of the top 40 HCPCS/CPT codes[17] billed in 2009,[18] 20 were for injectable drugs. Of the remaining 20 codes, five codes were associated with ambulance transport billings, one was for mammography screening, one was for blood glucose tests, one was for power wheelchairs, one concerned flu vaccines, one involved enteral feeding supplies, one concerned hospital beds and two involved oxygen

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16 DRG 871, the third-most expensive DRG, covers septicemia or severe sepsis, which is usually treated in an ICU unit. It seems highly unlikely that such hospitalizations are deferrable.

17 "HCPCS" stands for Healthcare Procedural Coding System, which is a system maintained by CMS for reporting the medical services received by Medicare beneficiaries. "CPT" stands for Current Procedural Terminology, a system maintained by the American Medical Association to provide a uniform language for describing and reporting professional services.

18 The highest paid CPT code, advance life support ambulance transportation, accounted for $1,849,098,741; the 20th highest, injection of pemetrexal, was only $240,490,178; and the 40th, for negative pressure wound therapy pumps, was only $141,143,581.

delivery systems. In short, *aside from taking steps to control the drug injection billings*, ACO management will not be able to readily control expenses by central management directives.

The table below reflects, by charges per patient, the top 14 billed HCPCS codes for 2009. Billing for these 14 HCPCS codes accounts for 9% of the Part B charges for all services in 2009, incurred in connection with treating only 1.6% of the beneficiaries. Half of the charges are for injectable drugs.

Code	Description	% of Persons Served	Total Charges	Charge/ Patient
J9310	Rituximab	0.100	$851,245,000	$18,635
77418	Radiation treatment delivery	0.100	$645,418,000	$14,375
J1745	Injection, infliximab	0.050	$624,825,000	$14,311
J2778	Injection, ranibizumab	0.100	$859,561,000	$9,146
J2505	Injection, pegfilgrastim	0.050	$521,463,000	$7,939
J9035	Injection, bevacizumab	0.050	$780,392,000	$5,094
K0823	Power wheelchair	0.050	$556,972,000	$3,616
J0881	Injection, darbapoetin alfa	0.050	$452,028,000	$3,585
J0885	Injection, epoetin alfa	0.100	$373,736,000	$2,855
90960	ESRD-related services	0.100	$569,014,000	$2,081
66984	Cataract removal	0.200	$2,130,592,000	$1,832
27447	Arthroplasty, knee	0.050	$400,146,000	$1,636
E1390	Oxygen Concentrator	0.600	$1,779,670,000	$1,230
		1.600	$10,545,062,000	
			9% of total	
T:		**100.000**	**$117,586,191,000**	

Each time an ACO physician prescribes the use of an injectable pharmaceutical for treatment of the patient, the physician will be increasing the Medicare Part B charge allocation to the ACO's patient population and thus reducing the shared savings potential. Where there are multiple treatment options available to a physician and the injectable drug is one of several choices, it can be expected that rational ACO management will pressure physicians across all specialties to defer use of injectable drug treatments. A quick comparison between these injectable charges and the charges to Medicare for an office visit further illustrates this point. The average charge to the Medicare program for a patient visit with a physician billed under the most frequently used code (99214) was $318 in 2009. In order to save $18,365, the cost of drug injections for one patient under J9310 — the ACO would have to eliminate 58 office visits.

Conclusion

In sum, we project that by virtue of the economic incentives built into the ACO statute and proposed regulations, particularly with the exclusion of drug and device companies from participation in those entities, ACOs will seek to earn shared savings for their members from the Medicare program through charge reduction measures that will negatively impact sales of drugs and devices. While the proposed rule contains some protections against blatant cost-shifting or care denial (or delay) strategies, the complexity and subjectivity of the quality standards may be insufficient to deter subtler strategies that negatively impact patient care in pursuit of shared savings payments, which could negatively impact manufacturers of products that, in isolation, may be perceived to be high cost, but actually improve patient care and reduce overall health care spending. Pharmaceutical and medical makers need to analyze and understand the likely impact of the proposed ACO rules and engage policymakers and others to ensure the promise of higher quality and more effective health care becomes a reality. Manufacturers also should consider whether the proposed rules should be modified to provide more flexible ACO models that would allow — and encourage — manufacturers to be more direct participants in the ACO model, so that these companies would have a seat at the table in determining how best to meet the shared savings program's goals of better health care for individuals and populations and reduced overall health care expenditures. The regulations are not yet final and comments to the proposed regulations may be submitted until June 6. Please contact us if you would like assistance in submitting comments.

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