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Medicare Shared Savings Program: Issues of Interest for Pharmaceutical and Medical Device Manufacturers




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The Centers for Medicare & Medicaid Services (CMS) recently released its Final Rule implementing the Medicare Shared Savings Program (MSSP) for Accountable Care Organizations (ACOs).[1] On the same day that CMS released the MSSP Final Rule, CMS and the Department of Health and Human Services Office of Inspector General (OIG) together released a separate Interim Final Rule with comment period outlining five waivers that protect ACOs participating in the MSSP from liability under federal fraud and abuse laws in certain circumstances.[2]

While these rules focus chiefly on providers and suppliers that are eligible to participate in Medicare ACOs, the MSSP and the accompanying fraud and abuse waivers may affect many other stakeholders in the U.S. health care system, including pharmaceutical and medical device manufacturers. As an important reform initiative authorized by the 2010 health care reform law, ACOs will be accountable (in certain ways) for the quality and costs of care for the Medicare beneficiaries who receive their primary care from providers participating in the ACO.[3] CMS anticipates that ACOs will serve one to five million Medicare beneficiaries in their first several years of operation alone.[4]

This article highlights aspects of the MSSP Final Rule and the Waiver Interim Final Rule that are of particular interest to pharmaceutical and medical device manufacturers.

Potential Impact of the Shared Savings Program on Drug and Device Utilization

The MSSP has the potential to affect drug and device utilization in several ways, particularly through the introduction of shared savings (or losses) between ACO participants and Medicare. Under the MSSP, CMS will track the costs to Medicare of services provided to Medicare beneficiaries assigned to participating ACOs. If an ACO meets certain quality standards, it will be able to share in any cost savings to the Medicare program for its assigned beneficiaries. Depending on the ACO's choice between two financial models CMS offers, it could also be financially liable for any cost over-

[1] Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations, 76 Fed. Reg. 67802 (Nov. 2, 2011) (MSSP Final Rule).

[2] Medicare Program; Final Waivers in Connection With the Shared Savings Program, 76 Fed. Reg. 67992 (Nov. 2, 2011) (Waiver Interim Final Rule).

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[3] Patient Protection and Affordable Care Act § 3022, Pub. L. 111-148, 124 Stat. 119, as amended by the Health Care and Education Reconciliation Act of 2010 § 10307, Pub. L. 111-152, 124 Stat. 1029 (PPACA).

[4] MSSP Final Rule, 76 Fed. Reg. at 67965.

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runs.[5] The savings (or losses) in which ACOs will share during a particular year generally equal the ''benchmark,'' which is an estimate of what the Medicare Part A/Part B spending for the ACO's patient population would have been for that year without the ACO, minus the actual Part A/Part B spending for the beneficiaries assigned to the ACO for that year.

Other things being equal, an ACO would therefore have an incentive to reduce spending on Part B-reimbursable drugs and devices but not Part D drugs, because Part D costs will not affect the shared savings or losses calculation. Thus, certain drugs may benefit from the existence of ACOs, such as Part D drugs that (1) reduce the need for Part A/B expenditures, and (2) do so in the short term (ideally, within the same calendar year that the drug is prescribed, to maximize the chance that the patient will be attributed to the ACO during the period when the cost savings are experienced).[6] For example, a Part D drug that is prescribed after a hospital stay and that reduces the likelihood of readmission would benefit from the ACO model. That drug could benefit even more from ACOs if its competitors are Part B drugs, or if a Part B-reimbursable device could be substituted for the Part D drug, because then ACO participants may have incentives to shift Medicare patients from the Part B competitors to reduce Part A/Part B costs of beneficiaries assigned to the ACO and potentially increase the ''savings'' Medicare shares with the ACO. A Part B drug or device that succeeds in reducing total Part A/Part B spending could also benefit from ACOs' incentive to reduce Part A/Part B costs, but the Part B drug or device's own costs would count in the calculus.

In the MSSP Final Rule, CMS points to some factors that would limit such substitutions. CMS ''believe[s] that the program's quality measurement and program monitoring activities will help us to prevent and detect any avoidance of appropriately treating at-risk beneficiaries.''[7] Further, CMS states, ''to the extent that [ ] lower cost therapies are not the most appropriate and lead to subsequent visits or hospitalizations under Parts A and B, then any costs associated with not choosing the most appropriate treatment for the patient would be reflected in the ACO's per capita expenditures.''[8]

ACOs could also affect drug or device use because the chance to share in Part A/Part B savings could encourage ACO participants to reduce Part A and B covered services to Medicare patients. To reduce the risk that ACOs would limit medically necessary services (including drugs and devices) covered by Parts A and B, CMS has incorporated several safeguards into the MSSP. For example, the Final Rule imposes a cap on the shared savings available to an ACO: (1) 10 percent of the ACO's benchmark, for ACOs operating under the one-sided model (as explained in footnote 5); and (2) 15 percent of the benchmark, for ACOs operating under the two-sided model. CMS rejected certain commenters' requests to remove the sharing caps entirely, stating that ''retaining the performance payment limits is necessary to comply with the statute and important for ensuring against providing an overly large incentive that may encourage an ACO to generate savings through inappropriate limitations on necessary care.''[9]

An ACO must also satisfy CMS quality requirements before it can share in any savings it generates. In the MSSP Final Rule, CMS adopted a total of 33 quality measures, a significant reduction from the 65 measures in the proposed rule. Generally, ACOs must achieve the specified minimum attainment level on at least 70 percent of the measures in each of four measure domains in which the 33 measures are grouped in order to share in any savings attributed to its assigned beneficiaries and continue in good standing in the program. (For the first year of the program, however, ACOs will receive full credit for *reporting* the required quality measures, irrespective of how well they perform on the measures. Certain quality measures also will be phased in over the second or third performance years and the ACOs will again receive full credit for simply reporting those measures in those years).[10] CMS also will base the percentage of shared savings an ACO obtains on the ACO's quality score. For example, if the ACO is operating under the ''two-sided'' shared savings model, it is eligible to earn up to 60 percent of the shared savings; therefore, if it earns a 90 percent quality score, it would get 54 percent of the maximum possible shared savings (90 percent of 60 percent, or 54 percent).[11]

These quality requirements may help to reduce the incentive for ACOs to focus strictly on cost-cutting, and create a more balanced set of incentives that reduces the risk of suboptimal care. Manufacturers, however, should examine CMS's list of quality measures to determine whether or to what extent the measures are relevant to their products (particularly the measures in the Preventive Health and At-Risk Populations domains). The scope of the 33 measures adopted by CMS is necessarily small in relation to the range of diseases and conditions for which Medicare beneficiaries are treated.[12] CMS has noted, however, that it expects to expand the quality measures ''to include other highly prevalent conditions and areas of interest, such as frailty, mental health, substance abuse, including alcohol screening, as well as measures of caregiver experience,'' and that it will ''add and retire measures as appropriate through the rulemaking process.''[13] Thus, Part B drug and device manufacturers should watch for future opportunities to comment on the adoption of ad-

[5] Participating ACOs may choose between two tracks with varying risks and rewards. Track 1 offers a pure ''one-sided'' shared savings option, in which participating ACOs will be able to share in savings but will not be at risk during the initial agreement period if Medicare spending for their assigned beneficiaries exceeds benchmark expenditure levels. Track 2 offers a ''two-sided'' shared savings option, under which participating ACOs will be eligible for a higher share of achieved savings than would be available under Track 1, but will be at risk for losses for all years of their agreements. *Id.* at 67904-09.

[6] Based on experience from its physician group practice demonstration, CMS expects about a 25% variation in an ACO's attributed patient population from year to year. *Id.* at 67861.

[7] *Id.* at 67920.

[8] *Id.*

[9] *Id.* at 67936.

[10] Table 1 of the MSSP Final Rule lists the quality measures and their pay for performance phase-in schedules. *See id.* at 67889-90.

[11] *Id.* at 67899. ACOs operating under the pure ''one-sided'' model are eligible to earn up to 50% of the shared savings; therefore, if such an ACO earned a 90% quality score it would get 90% of the maximum possible shared savings (90% of 50%, or 45%). *See id.*

[12] *See id.* at 67889-90.

[13] *Id.* at 67873, 67888.

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ditional quality measures that could counteract incentives for underutilization of their products.

Potential Impact of the Shared Savings Program on the 340B Program

The 340B drug pricing program (named after a section of the Public Health Service Act that establishes the program) allows certain ''covered entities'' to purchase covered outpatient drugs at a statutorily defined discount and dispense those discounted drugs to their own ''patients.''[14] Several aspects of the MSSP Final Rule limit the impact of the MSSP on the scope of the 340B program.

Importantly, the Final Rule eliminates certain incentives outlined in the proposed rule for ACOs to steer patients to covered entities. For example, in order to encourage ACOs to include Federally Qualified Health Centers (FQHCs), which are 340B-eligible, and Rural Health Clinics (RHCs), which are not 340B-eligible, as participants, the proposed rule would have provided a sliding scale-based increase in the shared savings rate, of up to 2.5 percent under the ''one-sided'' shared savings model and up to 5 percent under the ''two-sided'' model, for ACOs that included an FQHC or RHC as a participant.[15] The exact number of extra points would have depended on the number of Medicare fee-for-service beneficiaries who received care from an FQHC or RHC participant.[16] The proposed rule would have further encouraged ACOs to steer beneficiaries to FQHCs, RHCs, or Critical Access Hospitals (CAHs) (which may be 340B-eligible) by allowing ''one-sided'' ACOs in which at least 50 percent of beneficiaries had at least one encounter with an FQHC, RHC, or CAH participant to share in savings on a ''first dollar'' basis.[17]

The MSSP Final Rule, by contrast, does not adopt the proposal to increase the shared savings rate for including FQHCs or RHCs as ACO participants.[18] The MSSP Final Rule also allows all ACOs to share in savings on a ''first dollar'' basis, so there is no longer any need for a net savings threshold exemption based on beneficiary encounters with FQHC, RHC, or CAH participants. Together, these changes reduce incentives for ACOs with multiple entities to steer patients to FQHC, RHC, and CAH participants. On the other hand, the MSSP Final Rule allows FQHCs and RHCs independently to form ACOs, which they would not have been able to do under the proposed rule.

However, certain changes in the MSSP Final Rule may encourage ACO referrals to Disproportionate Share Hospitals (DSHs), another category of entity that may be 340B-eligible. The MSSP Final Rule removes the special payments that Medicare makes to DSHs from the benchmark and actual spending figures that are used to measure Medicare's savings from an ACO (as discussed above, the savings attributed to an ACO equal the ''benchmark'' Medicare Part A/B spending for the ACO's beneficiaries that would have occurred without the ACO, minus the actual Part A/B spending for the ACO's beneficiaries that occurred with the ACO). CMS excluded the special DSH payments because these higher payments ''could create incentives for ACOs to avoid appropriate referrals to [DSH] hospitals in an effort to demonstrate savings.''[19] However, CMS notes that it ''plan[s] to monitor this issue to help us determine whether these adjustments should be maintained and may revisit it in future rulemaking as we gain more experience with the [MSSP].''[20]

Certain commenters also expressed concerns that the MSSP could contribute to the inappropriate expansion of the 340B program, because ''ACOs, ACO participants, and ACO providers/suppliers who also participate in the 340B program . . . may purchase and administer drugs for patients of other ACO participants and providers/suppliers.''[21] CMS responded to these concerns in the MSSP Final Rule, emphasizing that:

> The ACO is not itself a 340B eligible entity. Health care providers in an ACO that participates in the 340B program must continue to meet all the requirements of the 340B statute, including ensuring they are not diverting drugs to non-patients or receiving duplicate discounts. A 340B provider is prohibited from purchasing or transferring drugs to non-340B entities and patients of non-340B providers, including those which are a part of an ACO.[22]

Additional guidance from the Health Resources & Services Administration (HRSA) regarding the 340B ''patient'' definition could help ensure that the MSSP Final Rule does not unintentionally contribute to expanding the 340B program beyond its purpose of providing discounted drugs to 340B covered entities to treat their low-income, uninsured ''patients.'' HRSA had been expected to develop new guidance to define a 340B ''patient'' (a notice defining patient was reviewed by OMB, but has not been released).[23]

In a recent submission to Senator Charles Grassley responding to an inquiry regarding the 340B program, HRSA stated that it ''is reviewing the patient definition guidance. If HRSA determines a new patient definition is needed, it would be published as a proposed guidance and/or a proposed regulation depending on the scope of the definition.''[24]

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[14] *See* 42 U.S.C. § 256b.

[15] Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations, 76 Fed. Reg. 19528, 19614 (April 7, 2011) (MSSP Proposed Rule).

[16] *Id.*

[17] In other words, such ACOs would be exempt from the ''net savings threshold requirement,'' under which ACOs may only share in savings that exceed a specified savings threshold. *Id.* at 19613.

[18] MSSP Final Rule, 76 Fed. Reg. at 67859.

[19] *Id.* at 67921.

[20] *Id.* at 67922.

[21] *Id.* at 67956.

[22] *Id.*

[23] The existing 340B ''patient'' definition generally requires that: (1) the covered entity have a relationship with the individual ''such that the covered entity maintains records of the individual's health care''; (2) the individual receives health care services from a health care professional who is an employee of the entity or provides care under contract or other arrangements with the 340B entity, ''such that responsibility for the care provided remains with the covered entity''; and (3) the individual receives care from the covered entity that is consistent with the service or range of services for which the entity receives federal grant funding or FQHC look-alike status. 61 Fed. Reg. 55156 (Oct. 24, 1996). HRSA also published a proposed (but never finalized) clarification of the patient definition in 2007. 72 Fed. Reg. 5243 (Jan. 12, 2007).

[24] Letter from Mary K. Wakefield, Admin., HRSA, to Hon. Charles E. Grassley, Ranking Mem., Senate Comm. on the Ju-

In connection with the development of that guidance (if such guidance is determined to be necessary), HRSA will have the opportunity to clarify that beneficiaries assigned to a covered entity ACO are not ''patients'' of the covered entity unless they satisfy the patient definition with respect to that covered entity, and it will remain true that the covered entity can only use those drugs to treat its own patients (not patients of other ACO participants, who do not become patients of a 340B entity merely because their *own* health care provider joins an ACO that also includes the 340B entity).

Similarly, new patient guidance would provide HRSA the opportunity to clarify that ACO participants do not become ''integral parts'' of a covered entity (or otherwise obtain covered entity status), by virtue of the fact that they participate in an ACO with a covered entity. In the hospital context, HRSA has issued guidance providing that outpatient facilities that qualify as ''integral parts'' of a covered entity hospital are treated as part of the covered entity, and therefore can purchase 340B drugs and provide those drugs to their own patients. Under HRSA's existing guidance, an outpatient facility qualifies as an ''integral part'' of a DSH hospital only if it is included on the cost report of the hospital, and a 340B hospital that files Medicare cost reports must certify on its 340B registration form that each outpatient facility listed is reimbursable on its cost report.[25] Therefore, a health care provider does not become an ''integral part'' of a 340B hospital by joining an ACO in which the 340B hospital participates, nor is the ACO itself an ''integral part'' of such a hospital, unless it appears on the 340B hospital's Medicare cost report.

To date, HRSA has not issued guidance creating an analogue to the ''integral part'' theory for 340B entities other than hospitals.[26] Such an analogue would help reduce the risk of confusion and violation of 340B antidiversion rules, by making clear that a 340B entity's participation in an ACO does not make the ACO itself or any other participants in the ACO eligible to acquire 340B drugs or to give their patients access to 340B drugs; the 340B covered entity will remain the only entity that can purchase 340B drugs.

Potential Impact of ACO Fraud and Abuse Waivers on Drug and Device Manufacturers

The Waiver Interim Final Rule sets forth five waivers of federal fraud and abuse laws, to encourage health care providers to form ACOs envisioned by the MSSP. These waivers provide protection under one or more of the following laws: the Provider Self-Referral Law (the Stark Law), the federal Anti-Kickback Act (AKA), the Gainsharing Civil Monetary Penalties (CMP) law, and the Beneficiary Inducement CMP law. These waivers are self-implementing (i.e., there is no filing or application requirements for the waivers), and an arrangement need only comply with one of the waivers in order to be protected.[27] The waivers apply uniformly to each ACO, ACO participant, and ACO provider/supplier (as those terms are defined in the MSSP Final Rule).[28] Below, we briefly outline the requirements for each of the five waivers and highlight certain issues of interest for pharmaceutical and medical device manufacturers.

ACO Pre-Participation Waiver

The ACO Pre-Participation Waiver waives the Stark Law, the Gainsharing CMP, and the AKA with respect to start-up arrangements that predate an ACO's participation agreement with CMS, provided that all the following conditions are met: (1) the parties have a good-faith intent to develop an ACO that will participate in the MSSP in a particular year; (2) the parties are taking diligent steps to develop an ACO that would be eligible for a participation agreement that would become effective during the target year; (3) the ACO's governing body has made and duly authorized a *bona fide* determination that the arrangement is reasonably related to the purposes of the MSSP; (4) the arrangement, its authorization by the governing body, and the diligent steps to develop the ACO are contemporaneously documented; (5) the description of the arrangement is publicly disclosed in a manner established by CMS (the description shall not include the financial or economic terms of the arrangement); and (6) if an ACO does not submit an application for a participation agreement by the last available application date for the target year, the ACO must submit a statement on or before the last available application date, in a form and manner to be determined by CMS, describing the reasons it was unable to submit an application.[29] The Pre-Participation Waiver is effective on November 2, 2011, for target year 2012, or one year proceeding an application due date for a target year of 2013 or later, and would generally end on the start date for the agreement. An ACO may use the Pre-Participation Waiver only one time.[30]

Notably, start-up arrangements involving drug and device manufacturers are excluded from the Pre-

diciary (Oct. 21, 2011), *available at*: http://www.grassley.senate.gov/about/upload/Final-signed-Grassley-340B-package-10-21-11.pdf.

[25] 59 Fed. Reg. 47884, 47885 (Sept. 19, 1994) (''This [cost report] test clearly determines whether a facility is an integral part of a DSH hospital, and is an appropriate standard to determine [340B] eligibility.''). These facilities must be registered with HRSA and listed in the 340B database.

[26] HRSA's instructions to non-hospital covered entities for completing the 340B registration form do include a note on registration of ''satellite facilities'': ''Please be advised that [HRSA] requires that all satellites of an entity be registered in the program in order for patients of those satellites to be eligible to receive 340B drugs. Only patients of a covered entity may receive drugs purchased under 340B. You may not order drugs from one facility to distribute to patients of another satellite.'' HRSA, *Instructions for Completing the 340B Registration Form (not for use by Disproportionate Share Hospitals, STD, or TB entities)* 1 (Jan. 24. 2005), *available at*: ftp://ftp.hrsa.gov/bphc/pdf/opa/PrgmReg.pdf. But this note presumably just means that facilities associated with a covered entity must be independently eligible for 340B, and registered in 340B, to receive 340B drugs.

[27] Waiver Interim Final Rule, 76 Fed. Reg. at 67999.

[28] *Id.* The definition of an ACO provider/supplier does not include a pharmaceutical or medical device manufacturer. *See id.* at 67974. (''*ACO provider/supplier* means an individual or entity that—(1) Is a provider (as defined at [42 C.F.R. § 400.202]) or a supplier (as defined at [42 C.F.R. § 400.202]); (2) Is enrolled in Medicare; (3) Bills for items and services it furnishes to Medicare fee-for-service beneficiaries under a Medicare billing number assigned to the TIN of an ACO participant in accordance with applicable Medicare regulations; and (4) Is included on the list of ACO providers/suppliers that is required under § 425.204(c)(5).'')

[29] *Id.* at 68000.

[30] *Id.*

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Participation Waiver. The Waiver Interim Final Rule provides that the ''pre-participation waiver does not cover arrangements involving drug and device manufacturers, distributors, DME suppliers, or home health suppliers. Drug and device manufacturers and distributors are not Medicare enrolled suppliers and providers; DME and home health suppliers have historically posed a heightened risk of program abuse.''[31] This decision seems particularly puzzling because the Waiver Interim Final Rule suggests the possibility that certain arrangements involving drug and device manufacturers may be protected under the ACO Participation Waiver, as discussed further below. Moreover, to the extent that drug manufacturers are party to arrangements with hospitals or other providers who are seeking to participate in an ACO, it is unclear how the Pre-Participation Waiver would affect such arrangements, if at all.

ACO Participation Waiver

Under the ACO Participation Waiver, the Stark Law, the Gainsharing CMP, and the AKA are waived with respect to any arrangement of an ACO, one or more of its ACO participants or its ACO providers/suppliers, or a combination thereof, provided that: (1) the ACO remains in good standing under its participation agreement; (2) the ACO meets the governance, leadership, and management requirements set forth in the MSSP regulations; (3) the ACO's governing body has made and duly authorized a *bona fide* determination that the arrangement is reasonably related to the purposes of the MSSP; (4) both the arrangement and its authorization by the governing body are contemporaneously documented; and (5) the description of the arrangement is publicly disclosed in a manner established by CMS (the description shall not include the financial or economic terms of the arrangement). The Participation Waiver will start on the date of the participation agreement and will end six months following expiration or termination of the participation agreement.[32]

The language of the Waiver Interim Final Rule suggests that the ACO Participation Waiver may extend to drug and device manufacturers (unlike the other fraud and abuse waivers in the Waiver Interim Final Rule). In particular, the Waiver Interim Final Rule expressly seeks ''comments on whether we should add additional conditions to the participation waiver—such as conditions requiring commercial reasonableness or fair market value or prohibiting exclusivity—that would apply to ACO relationships with outside parties, such as laboratories, equipment or supply companies, drug and device manufacturers, or distributors or purchasing organizations.''[33] Moreover, the fact that manufacturers are specifically excluded from the Pre-Participation Waiver suggests that they are not so excluded from the Participation Waiver.

The language of Waiver Interim Final Rule is not completely clear, however. In another passage, CMS states that the Participation Waiver applies to ACO participants and ''ACO related arrangements with outside providers and suppliers, such as hospitals, specialists, or post-acute care facilities that might not be part of the ACO but have a role in coordinating and managing care for ACO patients.''[34] Drug and device manufacturers may not fall within the scope of these ''outside providers and suppliers'' protected by the waiver; even if they are, it is possible that the Participation Waiver protects ACOs in connection with arrangements with outside manufacturers, but does not protect the manufacturers themselves.

Shared Savings Distribution Waiver

Under the Shared Savings Distribution Waiver, the Stark Law, the Gainsharing CMP, and the AKA are waived with respect to distributions or use of shared savings earned by an ACO, provided that: (1) the ACO remains in good standing under its participation agreement; (2) the shared savings are earned by the ACO pursuant to the MSSP; (3) the shared savings are earned by the ACO during the terms of its participation agreement, even if the shared savings are actually distributed or used after the expiration of that agreement; and (4) the shared savings are distributed to or among the ACO's participants or its ACO providers/suppliers, or are used for activities that are reasonably related to the purposes of the MSSP.[35] Furthermore, with respect to waiver of the Gainsharing CMP, payments of shared savings distributions made directly or indirectly from a hospital to a physician may not be made knowingly to induce the physician to reduce or limit ''medically necessary'' items or services to patients under the direct care of the physician.[36]

CMS and OIG explain that they will interpret ''medical necessity'' for purposes of this waiver consistent with Medicare program rules and accepted standards of practice.[37] Because any Part B drugs or devices that are covered by Medicare must be medically necessary,[38] under this interpretation of ''medical necessity,'' any payment of shared savings distributions that induces a physician to limit the provision of Part B drugs or devices would not be protected by this waiver. However, CMS and OIG also state that distributions of shared savings by an ACO that incentivize the provision of *alternate and appropriate* medically necessary care consistent with the purposes of the MSSP are also protected by this waiver.[39] This statement could be interpreted to protect payments to physicians that induce them to substitute one medically necessary product for another. As such, this statement seems inconsistent with the text of the shared savings distribution waiver, which excludes payments made ''to induce the physician to reduce or limit medically necessary items or services.''

Allowing ACOs to incentivize physicians to substitute one medically necessary item or service for another could also interfere with independent clinical decision making, potentially compromising patient quality of care and undermining the goals of the MSSP. CMS and OIG have previously expressed concern about the risk that physicians will ''limit[] their use of quality-improving but more costly devices, tests, or treatments

[31] *Id.* at 68002.
[32] *Id.* at 68000-01.
[33] *Id.* at 68005.
[34] *Id.*
[35] *Id.* at 68001.
[36] *Id.*
[37] *Id.* at 68006.
[38] SSA § 1862(a)(1)(A) (Medicare statute's ''reasonable and necessary'' clause); *Medicare Benefits Policy Manual*, ch. 15, § 50.4 (2011).
[39] Waiver Interim Final Rule, 76 Fed. Reg. at 68006.

('stinting')'' as a result of shared savings distributions.[40] To mitigate this risk that physicians will stint on care, CMS and OIG could clarify in its Final Rule that the shared savings distribution waiver does not allow ACOs to distribute shared savings to induce physicians to substitute one medically necessary item or service for another. In addition, CMS and OIG could incorporate additional safeguards into the waiver for shared savings distributions to minimize physicians' incentives to limit patients' access to care.[41]

Compliance with Stark Law Waiver

Under the Compliance with Stark Law Waiver, the Gainsharing CMP and the AKA are waived with respect to any financial relationship between or among the ACO, its ACO participants, and its ACO providers/suppliers that implicates the Stark Law, provided all of the following conditions are met: (1) the ACO has entered into and remains in good standing under its participation agreement; (2) the financial relationship is reasonably related to the purposes of the MSSP; and (3) the financial relationship fully complies with a Stark Law exception.[42] Although compliance with a Stark Law exception does not generally immunize conduct under the AKA or Gainsharing CMP, CMS and OIG state that they are deviating from that principle in this waiver due to the specific safeguards in the MSSP, the statutory waiver authority, and a desire to minimize burdens on entities establishing or operating ACOs under the MSSP.[43]

Because the Stark Law only prohibits a ''physician'' from making a referral for certain designated health services to an entity with which the physician has a financial relationship, 42 U.S.C. § 1395nn, this particular waiver is of limited applicability to pharmaceutical and medical device manufacturers.

Waiver for Patient Incentives

Under the Waiver for Patient Incentives, the Beneficiary Inducement CMP and the AKA are waived with respect to items or services provided by an ACO, its ACO participants, or its ACO providers/suppliers to beneficiaries for free or below fair market value if all four of the following conditions are met: (1) the ACO remains in good standing under its participation agreement; (2) there is a reasonable connection between the items or services and the medical care of the beneficiary; (3) the items or services are in-kind; and (4) the items or services are preventive care items or services; or advance adherence to a treatment regimen, adherence to a drug regimen, adherence to a follow-up care plan, or management of a chronic disease or condition.[44] CMS and OIG specifically clarify that the Patient Incentive Waiver ''does not include financial incentives, such as waiving or reducing patient cost sharing amounts (that is, copayment or deductible), which we believe are prone to greater abuse.''[45]

Drug and device manufacturers *may not seek protection under the Waiver for Patient Incentives*, even if they are performing services or functions related to ACO activities. The Waiver Interim Final Rule explicitly provides:

> This waiver does not protect the provision of free or below fair market value items or services by manufacturers or other vendors to beneficiaries, the ACO, ACO participants, or ACO providers/suppliers. *The patient incentives waiver would cover ACOs, ACO participants, and ACO provider/suppliers that give beneficiaries items or services that they have received from manufacturers at discounted rates. However, the waiver would not cover the discount arrangement (or any arrangement for free items and services) between the manufacturer and the ACO, ACO participant, or ACO provider/supplier*.[46]

Thus, although the waiver could protect ACOs and providers participating in ACOs in connection with arrangements in which they ''give beneficiaries items or services that they have received from manufacturers at discounted rates,'' it does not protect drug manufacturers when providing these very same items to ACOs or ACO providers to provide to patients.

That is not to say that items distributed by manufacturers that promote adherence or disease management necessarily violate (or are ''suspect'' under) the fraud and abuse laws. The Waiver Interim Final Rule emphasizes that ''a waiver of a specific fraud and abuse law is not needed for an arrangement to the extent that the arrangement: (1) Does not implicate the specific fraud and abuse law; or (2) implicates the law, but either fits within an existing exception or safe harbor, as applicable, or does not otherwise violate the law.''[47] Thus, CMS and OIG may believe that no waiver is necessary to allow pharmaceutical manufacturers to provide (for example) the sorts of unbranded disease state and compliance educational materials that OIG has previously advised do not implicate the anti-kickback statute.[48] This is an issue we hope that OIG and CMS will confirm in the Final Rule.

Waivers for Center for Medicare & Medicaid Innovation Demonstrations

The five fraud and abuse waivers outlined in the Waiver Interim Final Rule are promulgated under the authority of PPACA § 1899(f), and as such only apply to ACOs participating in the MSSP, including the Advance Payment Initiative to be administered by the Center for Medicare & Medicaid Innovation (CMMI) (because such ACOs participate in the MSSP). However, PPACA § 3021 allows CMS to create waivers for certain CMMI demonstration programs (which might include Pioneer ACOs) and CMS and OIG state that they will address the exercise of that waiver authority in guidance relevant to those programs.[49]

CMMI has authority to waive certain otherwise-applicable statutory provisions ''as may be necessary solely for purposes of carrying out [Social Security Act

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[40] 73 Fed. Reg. 38502, 38548-58 (July 7, 2008); *accord* OIG Adv. Op. No. 09-06 (June 30, 2009); OIG Adv. Op. No. 08-16 (Oct. 14, 2008); OIG Adv. Op. No. 08-15 (Oct. 14, 2008); OIG Adv. Op. No. 08-09 (Aug. 7, 2008).

[41] *See id.* (highlighting safeguards).

[42] Waiver Interim Final Rule, 76 Fed. Reg. at 68001.

[43] *Id.* at 68006.

[44] *Id.* at 68001 and 68007.

[45] *Id.* at 68007.

[46] *Id.* (emphasis added).

[47] *Id.* at 67994.

[48] *See*, *e.g.*, OIG Advisory Opinion No. 11-07 (June 1, 2011); OIG Advisory Opinion No. 08-05 (Feb. 15, 2008).

[49] Waiver Interim Final Rule, 76 Fed. Reg. at 67994.

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§ 1115A] with respect to testing models.''[50] For example, CMMI may waive all requirements under Social Security Act Title XI, which includes fraud and abuse provisions such as the AKA, the Gainsharing CMP, and the Beneficiary Inducement CMP, in connection with testing models.[51] However, the statute also allows CMMI to *expand* demonstration models beyond the testing phase in certain cases, but does not authorize waivers for models expanded beyond the testing phase. Instead, its plain language only permits waivers ''necessary *solely for purposes of carrying out this section with respect to testing models* as described in subsection (b).''[52] The expansion provisions, by contrast, are separately set out in subsection (c). Manufacturers may wish to seek confirmation from CMS that CMMI fraud and abuse waivers do not apply during the model expansion phase.

Conclusion

ACOs have the potential to affect all of the stakeholders in the U.S. health care system, including pharmaceutical and device manufacturers. Manufacturers should continue to monitor new rules and developments related to ACOs and the MSSP and to evaluate how such developments may affect them.

[50] Social Security Act § 1115A(d)(1) (emphasis added).
[51] *Id.*
[52] *Id.* (emphasis added).