Complying with the Law of Unintended Consequences: How to Minimize the Risks of Liability and Litigation Before Signing MA Plan Shared Savings Agreements

Heather L. Stutz
Squire Patton Boggs (US) LLP
Columbus, OH

Reflecting on the problem with applying outdated laws to a changing atmosphere, it has been said that "good intentions can often lead to unintended consequences. It is hard to imagine a law intended for the workforce known to Henry Ford can serve the needs of a workplace shaped by the innovations of Bill Gates."[1] Although Representative Tim Walberg's (R-MI) example was aimed at the impact of applying historical employment laws to a radically different work environment, his observation is equally applicable to the evolving health care industry, both in terms of the way care is provided and the way services are reimbursed. In fact, through unintended consequences, existing and longstanding Medicare Advantage (MA) rules may actually stifle the innovation and collaboration newer laws like the Affordable Care Act (ACA) are meant to encourage.

Whatever the future of the ACA, most experts agree that some changes in the health care sector are here to stay. One change that is rapidly gaining widespread appeal both in governmental and commercial contexts is the move to value-based purchasing. The hybrid governmental/commercial plans—MA plans—are following suit. Unfortunately, outdated MA laws may compromise plans' and providers' ability to maximize the mutual value of value-based reimbursement, thereby reducing both parties' incentives to enter into the arrangements altogether.

MA plans and their contracting physicians should understand the laws affecting their value-based contracts so they can plan ahead and avoid: (1) liability for violating the laws; and (2) future disputes with each other about how to interpret and deal with the impact of the laws on their value-based reimbursement contracts.

One law that is impacting value-based contracts between physicians and MA Plans is 42 U.S.C. § 1395w-22(d)(4) and its implementing regulation 42 C.F.R. § 422.208. These sections govern physician incentive agreements with MA plans. They are intended to reduce any incentive for physicians to limit medically necessary services. While a laudable goal, the laws actually go further.

In addition to prohibiting incentives that reduce the provision of medically necessary services, 42 U.S.C. § 1395w-22(d)(4) and 42 C.F.R. § 422.208 also require any physician or group to have stop-loss coverage if they are at "substantial financial risk" as a result of a physician incentive plan. These substantial risk thresholds and stop-loss requirements have MA plans and physicians at odds with each other when negotiating and performing under shared savings agreements.

Shared Savings Payments Are Subject to Section 422.208

First, the parties often dispute whether the statute and regulation apply to shared savings contracts at all. The laws encompass virtually any incentive plan, including a shared savings plan. The statute defines "physician incentive plan" as "any compensation arrangement between a Medicare+Choice [nka Medicare Advantage] organization and a physician or physician group *that may directly or indirectly have the effect of reducing or limiting services* provided with respect to individuals enrolled with the organization under this part."[2] The regulation defines physician incentive plan substantially the same as in the statute.[3] Shared savings plans by design are intended to reduce unnecessary services and, therefore, fall within the definition of "physician incentive plan." As such, they must comply with the substantial risk thresholds and stop-loss requirements set out in the regulation at Section 422.208.

The regulation sets the following limits, among others: if a bonus payment is 33% or higher of all other payments to the physicians, or any "other incentive payment" is 25% or higher of all payments to the physicians, then the physicians are at "substantial financial risk."[4] There is no prohibition against physicians being at substantial financial risk and therefore agreeing to incentives in excess of the percentage thresholds.[5] However, once physicians are at substantial financial risk, they must have "adequate" stop-loss coverage, as detailed in the regulation, to curtail any monetary incentive they may have to withhold medically necessary services.[6]

So, is a shared savings payment a bonus or "other incentive payment?" Bonus is defined broadly as "a payment made to a physician or physician group beyond any salary, fee-for-service payments, capitation, or returned withhold."[7] Although a shared savings payment may fit this definition, a Centers for Medicare & Medicaid Services (CMS) representative confirmed that CMS does *not* consider shared savings payments to be "bonuses."[8] However, the representative also stated that where the shared savings payment relates to the use or cost of referrals outside the physician's own group, CMS would consider it to be an "other incentive payment" subject to the 25% threshold.[9] CMS' interpretation that shared savings payments are subject to the substantial risk thresholds is consistent with the regulatory history of Section 417.479, a sister regulation governing physician incentive payments from prepaid health care organizations and the

model for Section 422.208,[10] which suggests that the U.S. Department of Health and Human Services (HHS) intended to subject shared savings plans to the regulatory analysis and stop-loss safeguards.[11]

There are no cases or CMS guidelines pertaining to the application of Section 422.208 to shared savings arrangements. In fact, according to the CMS official, the regulation's application to shared savings agreements is an issue of first impression for CMS, growing out of the recent focus on shared savings agreements as a result of the Medicare Shared Savings Program and out of the fact that the enabling statute and regulation were enacted well before this new era of shared savings.[12] Only recently have interested parties started to inquire about the regulation's relationship to shared savings payments.

Exceptions to the Stop-Loss Coverage Requirements

Despite the broad interpretation of the types of payments that are subject to the statute and regulation, Section 422.208 is meant to provide safeguards so that *medically necessary* services are not limited or reduced in the process. The regulation, therefore, carves out certain incentive payments that are *not* subject to its stop-loss requirements.

First, payments that do not meet the applicable substantial risk thresholds are not subject to the stop-loss requirements.[13]

Second, payments that are not based on the use or cost of referrals *outside of the contracting physician group* (such as incentives based *solely* on the quality of care provided, patient satisfaction, and participation on committees or reduction of medically unnecessary services *within the group*) are not subject to the regulation.[14] Ancillary services are not considered referral services if they are performed by the physician group.[15] When a contract relates to both services furnished by the physician group as well as referral services, the contract is subject to the regulation, even though it may be hard to separate the two types of services.[16]

Third, physician groups serving panels of more than 25,000 patients are not at substantial financial risk.[17] In determining the panel size, the group may pool commercial, Medicare, and Medicaid enrollees or the enrollees of several MA organizations with which a physician or physician group has shared savings contracts.[18]

Minimizing Section 422.208 Disputes and Liability

In addition to understanding Section 422.208 to reduce the parties' risk of liability for government enforcement, addressing the regulation early can also curtail disputes between the parties. These party disputes occur at two primary points of the relationship:

- During negotiations when the MA plan wants to set a ceiling on the amount of savings the physician can receive under the shared savings plan by reference to the statute and regulation. A ceiling that does not measure up to the physician's expected efforts necessary to generate the savings could be an impediment to reaching a final agreement at all.
- After the fact when the shared savings payment is due. This timing is particularly ripe for disputes because the physician will have already expended resources generating the savings and may feel that the MA Plan is retroactively and improperly interpreting the physician incentive laws in an effort to rewrite the parties' agreement and retain more of the savings.

If the parties understand the requirements of, and exceptions to, Section 422.208 up front, the risk of these disputes can be minimized. Here are some ways to address Section 422.208 at the outset:

- If the provider intends to achieve cost savings *solely* through reductions, efficiencies, or quality improvements in its *own practice*, rather than through reductions in the cost or use of services *outside of the provider*, the agreement should reflect this fact because the savings generated and the corresponding payment will not be not subject to Section 422.208.
- If the contract relates to both services furnished by the provider (such as quality or satisfaction goals) as well as referral services, the contract is subject to the regulation, but the physician should be permitted to use only the portion related to referral services outside the provider to determine if the payment reaches the threshold. If the parties are able to estimate the portion of the savings attributable to referral services, and that amount does not reach the threshold, then no stop-loss should be required. Consider incorporating into the contract a procedure for calculating such an estimate, either in advance or when the payment is due, to avoid future disputes. CMS has also suggested that parties seek preapproval of the attribution process and their intent to apply some, but not all, of the payment to the threshold determination. The CMS representative expressed a willingness to grant the parties leeway in structuring the deal to avoid stop-loss requirements.[19]
- In addition, MA plans have the option to include a contract provision that would require the physician to specify the level of potential risk for referral services only.[20] Thus, the contract could be drafted to limit the physician's risk related to referral services outside of the physician's practice to less than the threshold, and leave the remainder of the shared savings payment unlimited, except as it relates to how the parties will share the savings.

- The physician group should consider whether it can pool patients to reach the 25,000 patient exception.

Complying With Stop-Loss Coverage Requirement

A practical difficulty of complying with the stop-loss requirements is that shared savings agreements do not lend themselves to a determination of the final payout amount in advance such that the parties would know whether the provider will meet the substantial risk threshold and need stop-loss coverage.

Another problem is that when stop-loss is required, the parties may dispute who is responsible for the cost of purchasing it. Under 42 C.F.R. § 422.208(d), the MA plan "must assure that all physicians and physician groups at substantial financial risk have either aggregate or per-patient stop-loss protection."[21] There is an argument that the plan must purchase or reimburse the provider for the cost of stop-loss. However, this position, though once embraced by CMS, has since been rejected by it. According to the regulatory histories of 42 C.F.R. § 422.208 and the related 42 C.F.R. § 417.479, and communications directly with CMS, its position now is that neither party is specifically obligated to purchase stop-loss protection—the parties are free to negotiate who must purchase the stop-loss coverage and the plan must determine and report whether and to what extent the provider has stop-loss protection.[22]

Faced with the prospect of a more limited payment than expected (perhaps not enough to cover the costs of performing under the contract) or the need to purchase stop-loss coverage, some physicians may choose not to enter into a shared savings agreement with an MA plan. This is discouraging because these arrangements have been proven to provide medical benefits as well as monetary savings. While complying with the laws as written, interested parties should also encourage lawmakers to remedy the disconnect between today's goals and yesterday's laws.

1 Education and the Workforce Committee Statement by U.S. Representative Tim Walberg, July 14, 2011, at the Hearing on "The Fair Labor Standards Act: Is It Meeting the Needs of the Twenty-First Century Economy?"
2 42 U.S.C. § 1395w-22(d)(4).
3 *See* 42 C.F.R. § 422.208(a).
4 *Id.* at (d)(3)(iii).
5 *Id.* at (c).
6 *Id.* at (c) and (f).
7 *Id.* at (a).
8 December 10, 2014 conference call with CMS Representative Marty Abeln.
9 *Id.*
10 *See* 63 Fed. Reg. 123, 35002 (Jun. 26, 1998); 65 Fed. Reg. 126, 40325 (Jun. 29, 2000).
11 *See* 61 Fed. Reg. 60, 13432 (Mar. 27, 1996). *See also* 61 Fed. Reg. 60, 13440 (Mar. 27, 1996) ("this final rule allows for continued, but limited, risk sharing beyond the point at which the stop-loss protection begins."); 61 Fed. Reg. 252, 69040 (Dec. 31, 1996) (referring to risk-sharing arrangements) (describing shared savings payments as bonuses). When commenters complained that withholds and bonuses should not be subject to the regulation, HHS responded that the laws broadly required stop-loss protection for *all forms of incentive arrangements* that put physicians at substantial financial risk. *See* 61 Fed. Reg. 252, 69045 (Dec. 31, 1996).
12 December 10, 2014 conference call with CMS Representative Marty Abeln.
13 42 C.F.R. § 422.208(c)(2).
14 61 Fed. Reg. 60, 13433 and 13447 (Mar. 27, 1996).
15 61 Fed. Reg. 252, 69041 (Dec. 31, 1996).
16 *See* 61 Fed. Reg. 60, 13439-40 (Mar. 27, 1996) (relating to § 417.479).
17 42 C.F.R. § 422.208(d)(3), (f)(2)(iii), and (g). *See also* 61 Fed. Reg. 60, 13439 (Mar. 27, 1996).
18 42 C.F.R. § 422.208(g).
19 December 10, 2014 conference call with CMS Representative Marty Abeln.
20 61 Fed. Reg. 252, 69040 (Dec. 31, 1996).
21 42 C.F.R. §§ 422.208(c)(2), (f)(1).
22 *Compare* Establishment of the Medicare+Choice Program, 63 Fed. Reg. 123, 35087 (Jun. 26, 1998) (requiring MA Plan to "provide" stop loss coverage) to Medicare+Choice Program, 65 Fed. Reg. 126, 40325 (Jun. 29, 2000) (replacing requirement that MA Plan "provide" stop-loss with duty to "assure" that physicians at substantial risk have stop-loss). *Compare* Requirements for Physician Incentive Plans in Prepaid Health Care Organizations, 61 Fed. Reg. 60, 13433 and 13448 (Mar. 27, 1996) (requiring plan to provide stop-loss protection directly, purchase it, or reimburse the cost if the physician group purchased it) and 61 Fed. Reg. 60, 13441 (Mar. 27, 1996) (CMS rejects requests to eliminate plan's responsibility for covering the stop-loss premium because doing so would be inconsistent with enabling statute) to 61 Fed. Reg. 252, 69036 and 69046 (Dec. 31, 1996) (eliminating requirement that the plan pay for stop-loss protection).