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Fraud and Abuse

A Fresh Look At The CMP Statute: It May Not Be As Proscriptive For Gainsharing Arrangements As The OIG Believes

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Introduction

The Medicare program increasingly is focused on improving the quality of care for its beneficiaries through various initiatives. Some initiatives include value-based purchasing (VBP) programs, which use payment incentives and transparency to increase the value of care by rewarding providers and suppliers for higher quality and more efficient services and for publicly reporting performance information. The Centers for Medicare and Medicaid Services (CMS) has developed a plan for hospital VBP^[2] and is in the process of developing a VBP plan for Medicare services of physicians and other professionals.^[3] The extant Physician Quality Reporting Initiative (PQRI)^[4] and the recently implemented Physician Resource Use Measurement and Reporting Program (PRU)^[5] are key building blocks for the

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establishment of physician value-based purchasing. Other VBP programs include the prohibition on paying hospitals for Hospital Acquired Conditions,[6] and the proposed National Coverage Determination that would prohibit paying for other “Never Events.”[7] Other initiatives include the various consumer-oriented tools to compare care given at one facility versus another.[8] Still other initiatives include various demonstration projects in the areas of aligning incentives (e.g., the physician/hospital gainsharing demonstrations), value based purchasing (e.g., the nursing home value based purchasing demonstration), care coordination (e.g., the Care Management for High Cost Beneficiaries Demonstration), prevention (e.g., Cancer Prevention and Treatment Demonstration for Ethnic and Racial Minorities), and health information technology (e.g., the Electronic Health Records Demonstration). The Patient Safety and Quality Improvement Act of 2005 (PSQIA) is another example of incentivizing voluntary reporting as a means of improving quality.[9] The PSQIA provides a mechanism by which hospitals, physicians, and other healthcare professionals can share sensitive patient safety information with “Patient Safety Organizations” (PSOs) on a confidential and privileged basis, so that such information can be aggregated and analyzed by the PSOs, which will then provide feedback and recommendations to healthcare providers.[10] At least some, and perhaps many, of the existing or potential VBP programs hold forth the promise of reducing costs while increasing quality.

A not-so-recent strategy for lowering costs is “gainsharing,” a term that traditionally has referred to programs between

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hospitals and physicians, under which hospitals pay physicians a portion of cost savings that physicians help achieve. Such programs have evolved to include measures that reward physicians for improving quality and are now better termed “incentive payment and shared savings programs.” In the calendar year (CY) 2009 Medicare Physician Fee Schedule (PFS) proposed rule, [11] CMS proposed an exception to the physician self-referral prohibition (Stark law) for incentive payment and shared savings programs. The physician self-referral law generally prohibits entities such as hospitals from providing remuneration to physicians who refer Medicare patients to them for certain services (such as inpatient or outpatient hospital services), unless an exception applies. In proposing an exception, CMS stated:

The Medicare program and private industry stakeholders are increasingly exploring the benefits of various types of gainsharing, pay-for-performance (“P4P”), value-based purchasing, and similarly-styled programs that use economic incentives to foster high quality, cost-effective care. Many of these programs involve payments from hospitals to physicians. These payments potentially implicate the fraud and abuse laws, including the physician self-referral statute. Existing exceptions to the physician self-referral statute, while useful, may not be sufficiently flexible to encourage a variety of nonabusive and beneficial gainsharing, P4P, and similar programs. [12]

Although CMS did not finalize an exception to the physician

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self-referral law for incentive payments and shared savings programs in the CY 2009 PFS final rule, it voiced its support for “an exception that is sufficiently flexible to encourage the development and implementation of beneficial, nonabusive incentive payment and shared savings programs that foster high quality, cost-effective care.” [13]

Regardless of whether CMS promulgates a new exception specifically tailored for incentive payment and shared savings programs, or whether parties avail themselves of existing exceptions, the physician self-referral law is only one hurdle for hospitals and physicians to leap. Two other statutes, administered by the Department of Health and Human Service’s (HHS) Office of Inspector General (OIG), also directly impact the ability of hospitals and physicians to engage in gainsharing arrangements involving Medicare patients. Of the two, the anti-kickback statute [14] arguably is the less difficult with which to contend, as it is an intent based statute. The Civil Monetary Penalty (CMP) statute, [15] at least as interpreted by the OIG, however, is extremely broad in its reach. As a result, parties that wish to engage in a gainsharing project and who want to be assured that the project will not subject them to sanctions under the CMP statute, have been required to either: (1) obtain an advisory opinion from the OIG that aspects of their gainsharing arrangement that implicate the CMP statute will not be subject to sanctions because, while technically in violation of the statute (in the OIG’s view), they are not abusive; or (2) in the absence of seeking an advisory opinion, be confident that their gainsharing arrangement is sufficiently similar to one that has received a favorable advisory opinion from the

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OIG.

Under the recently-departed Administration, HHS, including the OIG, generally supported non-abusive physician incentive and shared savings plans, but took the position that the CMP statute prohibits all gainsharing arrangements and that the only solution is for Congress to amend the statute. In this article, the author postulates that the CMP statute does not have to be read as prohibiting at least two non-abusive features of a hospital/physician gainsharing program, namely:

1. paying physicians to refrain from furnishing medically unnecessary services; and
2. paying physicians to use one medical supply or device rather than a clinically equivalent supply or device.

(This article does not address the issue of whether the CMP statute can be read reasonably to prohibit paying physicians to not provide medically reasonable services or to use one supply or device rather than its clinical equivalent; rather, this article is solely concerned with the issue of whether the CMP statute *must* be read in such a manner.)

Specifically, as argued below, the OIG's interpretation is not required by the plain language of the statute; rather, the plain language of the statute easily supports an interpretation that paying physicians to refrain from furnishing medically unnecessary services is permissible and even more easily supports an interpretation that paying physicians to use one supply or medical device rather than a clinically equivalent supply or device also is not prohibited

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by the statute. Moreover, contrary to the view expressed by the OIG, neither the legislative history of the original enactment of the CMP statute, nor the legislative history of the subsequent amendment to the CMP statute, sheds any light on the issue of whether paying physicians to refrain from providing medically unnecessary services is prohibited by the statute. Hopefully, to the extent that the new Administration is supportive of aligning hospital and physician incentives, HHS will find this article useful as providing the rationale for reading the CMP statute in a less restrictive manner.

Background

A. *The CMP statute*

Section 1128A(b)(1) of the Social Security Act, as codified at 42 U.S.C. § 1320a-7a(b)(1), provides that if a hospital (including a critical access hospital) knowingly makes a payment, directly or indirectly, to a physician as an inducement to reduce or limit services provided with respect to individuals who are entitled to Medicare or eligible for Medicaid and who are under the direct care of the physician, the hospital and physician shall be subject to civil monetary penalties assessments and exclusion from the federal healthcare programs. As originally enacted by the Omnibus Budget Reconciliation Act of 1986 (OBRA '86), the CMP statute was effective for payments by hospitals occurring more than six months after the date of enactment and was slated to be effective for payments by prepaid healthcare organizations occurring on or after April 1, 1989.^[16] However, the implementation date for prepaid healthcare

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organizations was extended to April 1, 1990 by section 4016 of the Omnibus Budget Reconciliation Act of 1987 (OBRA '87).[\[17\]](#) The date was further extended to April 1, 1991 by section 6207 of the Omnibus Budget Reconciliation Act of 1989 (OBRA '89).[\[18\]](#) Sections 4204(a) and 4731 of the Omnibus Budget Reconciliation Act of 1990 (OBRA '90) repealed the prohibition on incentive payments related to prepaid healthcare organization physician incentive plans and enacted specific requirements for regulating these plans.[\[19\]](#)

B. The OIG's Historical Approach to Gainsharing Arrangements

The OIG's interpretation of the CMP statute has been issued only in sub-regulatory materials thus far. The OIG issued a proposed rule in 1994,[\[20\]](#) but that rule was never finalized.[\[21\]](#) The principal piece of interpretive guidance on the CMP statute is the July 1999 Special Advisory Bulletin by the OIG. It is worth quoting at length from the Bulletin.

The statutory proscription is very broad. The payment need not be tied to an actual diminution in care, so long as the hospital knows that the payment may influence the physician to reduce or limit services to his or her patients. There is no requirement that the prohibited payment be tied to a specific patient or to a reduction in medically necessary care [emphasis added]. In short, any hospital incentive plan that encourages physicians through payments to reduce or limit clinical services directly or indirectly violates the statute.

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The breadth of the prohibition was intentional. As initially enacted by Congress, section 1128A(b)(1) of the Act prohibited payments by both hospitals and Medicare managed care plans to induce physicians to reduce clinical services. Section 1128A(b)(1) of the Act was subsequently amended to delete the reference to Medicare managed care plans, and to add a new subsection to section 1876 of the Act that permitted Medicare managed care plans to implement physician incentive plans, provided the managed care plan did not induce the reduction of medically necessary care to individual [emphasis in original] patients and did not place the physician at substantial financial risk for services not provided by the physician. Further, Congress explicitly gave the Secretary authority to regulate physician incentive plans offered by Medicare risk managed care plans. Because the resulting two provisions address the same issues and were drafted together, the stark difference in otherwise parallel language reflects a congressional decision to prohibit any payment arrangement between hospitals and physicians that is intended to induce a reduction or limitation in services.

This reading of the statute is also consistent with the legislative history surrounding the enactment of section 1128A(b)(1) of the Act. The prohibition was prompted in part by a General Accounting Office (GAO) report for the Chairman of the Subcommittee on Health of the House Ways and Means Committee regarding the physician incentive plans being implemented by

hospitals in response to the then-recently enacted diagnostic related group prospective payment system and their potential detrimental effects on quality of care for Medicare patients. The report analyzed four types of hospital-physician incentive plans, of which at least two bear strong similarities, and contain safeguards comparable, to the gainsharing arrangements currently being marketed by the healthcare consulting industry. While the GAO report discussed several features in these plans that reduced the incentive to give substandard care, it concluded that no combination of features could guarantee that such plans would not be subject to abuse.

Congress concurred. The House Committee Report that accompanied the House provision that became section 1128A(b)(1) of the Act stated that "[t]he Committee believes that such incentive payments may create a conflict of interest that may limit the ability of the physician to exercise independent professional judgment in the best interest of his or her patients." In explaining the inclusion of the prohibition in the final budget reconciliation bill that became OBRA 1986, the Chairman of the Subcommittee on Health of the House Ways and Means Committee, who was also a member of the Conference Committee, stated on the floor of the House that:

"[T]he House held firm in its insistence on outlawing certain physician incentive plans. We must not tolerate hospitals paying physicians to reduce or limit services

to the elderly."

In sum, we believe that section 1128A(b)(1) of the Act prohibits any hospital payments that induce physicians to reduce or limit clinical services to the physicians' patients.[\[22\]](#)

Thus worded, the Bulletin expresses the view that paying physicians to refrain from furnishing medically unnecessary services is prohibited by the CMP statute (while silent on the issue of paying physicians to use clinically equivalent medical devices), and that the OIG believed its interpretation of the CMP statute was compelled and not merely only one possible reading of the statute. The Special Advisory Bulletin was soon followed by an alert entitled "Recent Commentary Distorts HHS's IG Gainsharing Bulletin," which interpreted the 1994 proposed rule as having taken a hard-line approach consistent with the Special Advisory Bulletin[\[23\]](#) and took issue with a commentary that contended that the plain language of the statute required an incentive to induce physicians to withhold medically necessary services. The alert responded: "In our view, this interpretation is plainly wrong. Simply put, the language of the statute refers to 'services,' not 'medically necessary services.'" The view expressed in the 1999 Special Advisory Bulletin and the alert, that all forms of gainsharing are prohibited by the CMP statute, was echoed in 2005 testimony by the OIG before Congress.[\[24\]](#)

Although the 1999 Special Advisory Bulletin was hostile to the idea of issuing advisory opinions on proposed gainsharing arrangements, calling them "an inadequate and

inequitable substitute for comprehensive and uniform regulation in this area," [25] the OIG began issuing favorable advisory opinions in 2001 and has issued 14 favorable opinions to date, including 4 in 2008. [26] By 2005, the OIG was describing the subject arrangements as "significantly different from the black box arrangements discussed in the 1999 Special Advisory Bulletin." [27] In 2008, the OIG issued its first approval of a multi-year arrangement (up to this point all proposed arrangements were limited to one year). [28] Although the OIG has approved many arrangements, it has not changed its view that the CMP statute forbids all forms of gainsharing. Rather, for each proposed arrangement, it has analyzed the components and divided them into those that do not have clinical significance and thus do not implicate the CMP statute, and those that do have clinical significance but do not pose a risk of abuse. With respect to proposed arrangements in the latter category, the OIG has determined that although the proposed arrangement would violate the CMP statute, it would exercise its prosecutorial discretion and not seek sanctions. Along the way, the OIG reiterated its view that paying physicians to refrain from furnishing medically unnecessary services violates the CMP statute, [29] and explicitly declared that incentivizing physicians to use one medical supply or device rather than a clinically equivalent medical device (referred to as "product substitution" and "product standardization" in the advisory opinions) also violates the statute. [30] An analysis of the OIG's approach shows, however, that its reading is far from compelled.

Discussion

The OIG's positions, that Congress necessarily meant to prohibit hospitals from paying physicians to refrain from furnishing medically unnecessary care and necessarily meant to prohibit paying physicians to use less expensive but clinically equivalent supplies or devices, are not compelled by either the original enactment of the CMP statute or by the 1990 amendment to it

A. The plain language of the statute is ambiguous

The pertinent text of the CMP statute says simply that it is prohibited for a "hospital or a critical access hospital [to] knowingly make[] a payment, directly or indirectly, to a physician as an inducement to reduce or limit services." [\[31\]](#) The plain language of the statute, therefore, prohibits payments for inducements for actual reductions in services. The text does not, however, unambiguously prohibit paying physicians to refrain from furnishing unnecessary medical care or to use one medical supply or device rather than a clinically equivalent supply or device.

The statement in the 1999 Special Advisory Bulletin, "[t] here is no requirement that the prohibited payment be tied to . . . a reduction in medically necessary care," is a non-sequitur with respect to the issue of whether the OIG's interpretation is required by the statute. [\[32\]](#) That is, the fact that the statute does not on its face compel HHS to limit its reach to medically necessary services does not answer the question of whether HHS has the discretion to do so. Although it is true that the statutory language does not specify medically necessary care, it does not follow that the

only reading, or even the most natural reading, of the text is that “services” refers to both medically necessary and unnecessary care. “Services” easily can be read to mean medically necessary services due to the purpose of the statute and because dictionaries give, as one meaning of “service,” something of use or benefit.[\[33\]](#) In fact, it can be argued that it is counterintuitive to interpret a statute that was enacted to prevent patient abuse as prohibiting paying physicians to not provide medically unnecessary care, given that subjecting beneficiaries to unnecessary tests and procedures in itself can constitute patient abuse (physically and psychologically, and financially due to additional patient cost-sharing).[\[34\]](#) It is also not clear why the statute must be read to mean that a reduction or limitation in services equates to a change in a particular hospital’s medical policy (which OIG acknowledges could involve providing more care than necessary) as opposed to a reduction or limitation in recognized standards of care.

Moreover, the OIG’s view that “services” must be read literally and all-encompassing, so as to include medically unnecessary services, is at odds with its interpretations that “services” includes “items” and that “services” includes only *clinical* services. Just as the words “medically necessary” do not appear in the statute so as to (in the OIG’s view) not limit the reach to medically necessary services, so too does the statute not specify “clinical” services. Of course, given the purpose of the statute, it makes good sense to interpret the statute as applying to items and as applying only to clinical services, but, as noted above, the same could be said about interpreting it to apply only to medically

necessary services.

The OIG's textual argument appears especially weak with respect to its interpretation that the CMP statute prohibits paying physicians to use certain supplies or medical devices rather than clinically equivalent supplies or devices. That is, it is not immediately clear why paying a physician to use Supply A rather than Supply B, or Device C rather than clinically equivalent Device D is a reduction or limit in services. To the contrary, the statute can be read easily to say that, provided the patient receives one service instead of another service that carries the same procedure code, there is no violation of the CMP statute. And if one supply or device is of equal quality to another supply or device but simply costs less, there is even less reason to conclude that paying a physician to use the less expensive supply or device is contrary to the plain meaning of the CMP statute.

If common features of physician incentive plans prior to enactment of the CMP statute were to pay physicians for reducing medically unnecessary services and to use one supply or device rather than its clinical equivalent, *and* if Congress were aware that this was the case, one could argue that in OBRA '86 Congress was legislating against this background, and, therefore, the statutory language "reduce or limit services" could be read in context as including medically unnecessary services and as including clinically equivalent items due to the failure of Congress to make a distinction. But that does not appear to be the case. The 1986 GAO Report that the 1999 Special Advisory Bulletin credits as having partially prompted the 1986 enactment of

the statute first discusses in some detail existing physician incentive plans and then highlights certain features of those plans that it considered potential threats to the health of Medicare beneficiaries, but neither (1) paying physicians to not provide medically unnecessary services nor (2) paying physicians to use one device or supply rather than its clinical equivalent was mentioned as a feature of those plans or mentioned as a threat to beneficiaries' health.[\[35\]](#) In fact, the GAO Report contains language, albeit sparse, that suggests it was focusing Congress's attention away from unnecessary services and on incentives that might result in withholding necessary services.[\[36\]](#) Likewise, the Congressional Reports on OBRA '86, which can be fairly described as giving short shrift to the CMP statute provision, do not even mention paying physicians to refrain from furnishing medically unnecessary services or paying physicians to use clinically equivalent medical supplies or devices.[\[37\]](#)

B. The 1990 amendment to the CMP statute and its legislative history are not instructive, as a factual matter, as to what Congress meant in OBRA '86 by "reduce or limit services," and in any event, are not required, as a legal matter, to drive HHS's interpretation of the statute.

At the outset, it should be noted that the 1990 amendment to the CMP statute addressed Medicare managed care plans only and left undisturbed the statutory language prohibiting a "hospital or a critical access hospital [to] knowingly make [] a payment, directly or indirectly, to a physician as an inducement to reduce or limit services."[\[38\]](#) Thus, the

actions and statements of the OBRA '90 Congress with respect to the meaning of “reduce or limit services” are post-enactment. Post-enactment legislative “history” has often been denigrated—rightly so in the author’s opinion—as a poor indication of Congress’s intent in enacting a statute. [39] The 1999 Special Advisory Bulletin correctly notes that in OBRA '90, section 1128A(b)(1) of the Act was amended to delete the reference to Medicare managed care plans, and a new subsection was added to section 1876 of the Act that permitted Medicare managed care plans to implement physician incentive plans, provided the managed care plan did not induce the reduction of medically necessary care to individual patients and did not place the physician at substantial financial risk for services not provided by the physician. [40] The Special Advisory Bulletin also notes that “Congress explicitly gave the Secretary authority to regulate physician incentive plans offered by Medicare risk managed care plans.” [41] However, the conclusion that the Special Advisory Bulletin draws from these actions—that “[b]ecause the resulting two provisions address the same issues and were drafted together, the stark difference in otherwise parallel language reflects a congressional decision to prohibit any payment arrangement between hospitals and physicians that is intended to induce a reduction or limitation in services” [42]—is not compelled, either as a matter of fact or a matter of law, with respect to paying physicians to refrain from providing unnecessary services or to use one supply or device rather than a clinically equivalent supply or device.

The “resulting two provisions” (that is, sections 1128A(b)(1) and 1876(i)(8)) do *not* “address the same issues” and were

not “drafted together.” The fact that the OBRA ‘90 provision (which, of course, was not drafted at the time of the OBRA ‘86 provision) prohibited managed care plans from reducing medically necessary services as one of only several requirements a managed care incentive plan must meet in order to escape civil monetary penalties does not address the question of whether, under OBRA ‘86, a hospital or managed care organization was and is allowed to pay physicians to refrain from providing medically unnecessary care. That is, just because Congress in OBRA ‘90 effectively said we will let managed care plans have incentive payment programs provided they do no harm by withholding medically necessary care (and provided they meet other conditions), that does not translate into a finding by that Congress that the earlier OBRA ‘86 Congress meant to prohibit paying physicians for not providing medically unnecessary care. Had OBRA ‘90 amended the Act to provide specifically that managed care plans could pay physicians to refrain from furnishing medically unnecessary care, one could draw the inference that the OBRA ‘90 Congress read the CMP statute as prohibiting paying physicians for not providing medically unnecessary care. But that is not what happened.

Moreover, none of the Congressional reports on OBRA ‘90 states that the CMP statute applies to reductions in unnecessary services (or that it applies to paying physicians to use one supply or device rather than a clinical equivalent), and that the purpose of the amendment was to leave this restriction in place for hospital incentive plans while removing it for HMO incentive plans.[\[43\]](#) Of course,

the absence of such a statement might be explained if the OIG had gone on record as saying that the CMP statute applied to reductions in medically unnecessary services (or to paying physicians for using certain supplies or devices rather than clinical equivalents) and that Congress was aware of such an interpretation and was legislating in OBRA '90 against such a background, but that does not appear to be the case. The absence of such a statement also might be explained if a common feature of physician incentive plans prior to enactment of the statute was to pay physicians for reducing medically unnecessary services. If that were true, one could reason that in OBRA '90 Congress was legislating against this background and one could read the statutory language "reduce or limit services" in context as including medically unnecessary services due to the failure of Congress to make a distinction. But that also does not appear to be the case.

Finally, the statement in the 1999 Special Advisory Bulletin "Congress explicitly gave the Secretary authority to regulate physician incentive plans offered by Medicare risk managed care plans" does not add anything to the analysis. Irrespective of what specific delegations of rulemaking authority were added by Congress in OBRA '89 and OBRA '90, HHS always had (and continues to have) authority to interpret the language "reduce or limit services."[\[44\]](#)

Even if the Special Advisory Bulletin had gotten it right as a factual matter with respect to the views of the OBRA '90 Congress, however, it does not follow that, as a legal matter, Congress's action in OBRA '90 would prohibit HHS

from interpreting the CMP statute in a manner different than how the OBRA '90 Congress interpreted it. Whatever probative value exists in consulting post-enactment statements or actions by a subsequent Congress, an agency is not required to follow such statements or actions in interpreting the prior-enacted statute.

Two distinct but related tools of statutory construction are the reenactment and the acquiescence doctrines. Under the reenactment doctrine, when Congress reenacts legislation with the knowledge of a particular administrative interpretation of the previously enacted statute, the administrative interpretation is granted additional weight due to the perceived implied Congressional approval of the interpretation.[\[45\]](#) However, even where the reenactment doctrine is applicable, which does not appear to be the case here,[\[46\]](#) courts appear to have rejected the idea that an agency is prohibited from amending and altering its regulations without Congressional approval.[\[47\]](#)

It follows that if an agency is not required to continue an interpretation in the face of post-enactment action by Congress, it is not required to continue an interpretation due to post-enactment *inaction* by Congress. The acquiescence doctrine, under which Congress is said to have agreed with, or acquiesced in, an agency's construction of a statute, has been used successfully[\[48\]](#) and unsuccessfully[\[49\]](#) by agencies in defending their interpretations in litigation. Under certain circumstances, forbearance of a later Congress to amend a statute may provide persuasive evidence of what an earlier Congress meant, but the

doctrine, as a general tool of statutory construction, has serious shortcomings, [\[50\]](#) and, in any event, it does not serve as a positive law that prevents agencies from changing their interpretations, even interpretations (unlike the ones at issue here) that are set forth in regulations. Were it otherwise, Congressional inaction would transcend the Constitution and have the force and effect of law.

Conclusion

Unless a statute unambiguously compels a certain reading, agencies can, and should adapt their statutory interpretations as necessary to accommodate changing circumstances. [\[51\]](#) As demonstrated above, the CMP statute does not unambiguously prohibit hospitals from making incentive payments to physicians to refrain from furnishing unnecessary care or to use a particular supply or device rather than a clinical equivalent. Irrespective of whether a narrow approach to the CMP statute was warranted initially, the OIG's recent experience with the new generation of gainsharing arrangements, and the emphasis placed by Congress and HHS on increasing quality of care while at the same time reducing costs, argues in favor of the OIG taking a fresh look at the CMP statute and removing some unnecessary roadblocks to aligning hospital and physician incentives.

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[2] The Deficit Reduction Act of 2005, Pub. L. No. 109-171, § 5001(b), 120 Stat. 4, 29-30, (2006), required the development of a plan to implement VBP for Inpatient Prospective Payment System (IPPS) hospital services beginning fiscal year (FY) 2009. By statute, the plan must address: (a) the on-going development, selection, and modification process for measures of quality and efficiency in hospital inpatient settings; (b) the reporting, collection, and validation of quality data; (c) the structure, size, and source of value-based payment adjustments; and (d) the disclosure of hospital performance data. The Medicare Hospital VBP Plan Report to Congress is available on the CMS website at:

<http://www.cms.hhs.gov/AcuteInpatientPPS/downloads/HospitalVBPPIanRTCFINALSUBMITTED2007.pdf>.

The Medicare Hospital VBP Plan builds on the foundation of Medicare's current Reporting Hospital Quality Data for Annual Payment Update program, which, since FY 2005, has provided differential payments to hospitals that report their performance on a defined set of inpatient measures for public posting on the Hospital Compare website. If authorized by Congress, the VBP Plan would include both public reporting and new financial incentives to drive improvements in clinical quality, patient-centeredness, and efficiency. A full description of the Medicare Hospital VBP

Plan is contained in the FY 2009 IPPS final rule. 73 Fed. Reg. 48434, 48628-29 (Aug. 19, 2008).

[3] See Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), Pub. L. No. 110-275, § 131 122 Stat. 2494, 2520 (2008).

[4] Section 131(b) of MIPPA, *id.* at § 131(b), expanded on other recent legislation and made permanent the PQRI program, which is codified at §§ 1848(k)(2) and 1848(m) of the Social Security Act (the Act). 42 U.S.C. § 1395w-4(k) (2), § 1395w-4(m)). Under the PQRI program, physicians and certain practitioners can receive incentive payments for satisfactorily reporting data on specified quality measures for covered professional services.

[5] Section 131(c) of MIPPA, *supra* note 3, at § 131(c), amended § 1848 of the Act by adding subsection (n), which required the Secretary to establish and implement by January 1, 2009 a Physician Feedback Program using Medicare claims data and other data to provide confidential feedback reports to physicians (and as determined appropriate by the Secretary, to groups of physicians) that measure the resources involved in furnishing care to Medicare beneficiaries. If determined appropriate by the Secretary, the Secretary may also include information on quality of care furnished to Medicare beneficiaries by the physician (or group of physicians) in the reports. In April 2008, CMS awarded a contract to Mathematica Policy Research to assist in the development of physician resource use measures and confidential feedback reports. A detailed description of the PRU is contained in the CY 2009 Physician

Fee Schedule (PFS) final rule. 73 Fed. Reg. 69726, 69866-69 (Nov. 19, 2008).

[6] Section 5001(c) of Deficit Reduction Act of 2005, *supra* note 2, requires CMS to identify conditions that are: (a) high cost or high volume or both, (b) result in the assignment of a case to a diagnosis-related group (DRG) that has a higher payment when present as a secondary diagnosis, and (c) could reasonably have been prevented through the application of evidence-based guidelines. For discharges occurring on or after October 1, 2008, hospitals will not receive additional payment for cases in which one of the selected conditions was not present on admission. That is, the case would be paid as though the secondary diagnosis were not present. As explained by CMS in the FY 2009 IPPS final rule:

As one approach to combating [Hospital-Acquired Conditions (HACs)], including infections, in 2005 Congress authorized CMS to adjust Medicare IPPS hospital payments to encourage the prevention of these conditions. The preventable HAC provision at section 1886(d)(4)(D) of the Act is part of an array of Medicare value-based purchasing (VBP) tools that CMS is using to promote increased quality and efficiency of care. Those tools include measuring performance, using payment incentives, publicly reporting performance results, applying national and local coverage policy decisions, enforcing conditions of participation, and providing direct support for providers through Quality Improvement Organization (QIO) activities. CMS'

application of VBP tools through various initiatives, such as this HAC provision, is transforming Medicare from a passive payer to an active purchaser of higher value health care services. We are applying these strategies for inpatient hospital care and across the continuum of care for Medicare beneficiaries.

73 Fed. Reg. at 48471.

[7] According to the National Quality Forum (NQF), a not-for-profit membership organization created to develop and implement a national strategy for healthcare quality measurement and reporting, “never events” are errors in medical care that are clearly identifiable, preventable, and serious in their consequences for patients, and that indicate a real problem in the safety and credibility of a health care facility. See <http://www.psnet.ahrq.gov/primer.aspx?primerID=3>. Most of the HACs are considered to be never events, but CMS has determined that not all conditions included on the NQF list of Never Events can be adequately addressed by the HAC payment provision and therefore has proposed issuing National Coverage Determinations to declare the following events as not medically reasonable and necessary: wrong surgical or other invasive procedures performed on a patient; surgical or other invasive procedures performed on the wrong body part; and surgical or other invasive procedures performed on the wrong patient. More information is *available at* <http://www.cms.hhs.gov/apps/media/press/release.asp?Counter=1863>. Although the exact number of occurrences of “never events” is not known, they result in many deaths and

additional healthcare costs. In a 1999 study, the Institute of Medicine (IOM) estimated that as many as 98,000 deaths a year were attributable to medical errors, and recommended that error-related deaths be decreased by 50% over five years. L.T. Kohn, J.M. Corrigan, and M.S. Donaldson, eds., "To Err is Human: Building a Safer Health System, A Report of the Committee on Quality of Health Care in America," National Academy Press (Washington, DC 2000). A summary of the study is *available at*:

<http://www.iom.edu/Object.File/Master/4/117/ToErr-8pager.pdf>. Some states have enacted legislation requiring reporting of incidents on the NQF list. See Department of Health and Human Servs. Office of Inspector Gen., OEI-06-07-0041, "Adverse Events in Hospitals: State Reporting Systems" (Dec. 2008).

[8] The Hospital Compare, Nursing Home Compare, Home Health Compare, and Dialysis Facility Compare websites allow consumers to access information as to how well hospitals, nursing homes, home health agencies, and end stage renal disease (ESRD) facilities care for their patients. Hospital Compare provides information on how well hospitals care for patients with certain medical conditions or surgical procedures. See <http://www.hospitalcompare.hhs.gov/>. The Hospital Compare website was created through the efforts of CMS and the Hospital Quality Alliance (HQA). The HQA is a public-private collaboration established to promote reporting on hospital quality of care. The HQA consists of organizations that represent consumers, hospitals, doctors, employers, accrediting organizations, and federal agencies. Participation by hospitals is voluntary. See

<http://www.hhs.gov/faq/healthprograms/hospitalcompare/>. Nursing Home Compare contains a listing of poor performing skilled nursing facilities, known as “special focus facilities.” See <http://www.medicare.gov/NHCompare/>. Home Health Compare provides detailed information about how well Medicare-certified home health agencies provide care for some of their patients with respect to specified quality measures. See <http://www.medicare.gov/HHcompare/>. Dialysis Facility Compare provides information about the services and quality of care provided at dialysis facilities around the country. See <http://www.medicare.gov/dialysis>.

[9] Pub. L. No. 109-41, 119 Stat. 424 (2005).

[10] Final regulations implementing the PSQIA were published on November 21, 2008. 73 Fed. Reg. 70732 (Nov. 21, 2008).

[11] 73 Fed. Reg. 38502 (July 7, 2009).

[12] *Id.* at 38548.

[13] 73 Fed. Reg. 69726, 69798 (Nov. 18, 2008).

[14] Section 1128B(b) of the Social Security Act (42 U.S.C. § 1320a-7b(b)).

[15] Section 1128A(b)(1) of the Social Security Act (42 U.S.C. § 1320a-7a(b)(1)).

[16] Pub. L. No. 99-509, § 9313, 100 Stat. 1874 (1986).

[17] Pub. L. No. 100-203, § 4016, 101 Stat. 1330 (1987).

[18] Pub. L. No. 101-239, § 6207, 103 Stat. 2106, 2245 (1989).

[19] Pub. L. No. 101-508, §§ 4204(a) and 4731, 104 Stat. 1388 (1990).

[20] 59 Fed. Reg. 61571 (Dec. 1, 1994).

[21] Because the OIG has not issued a final rule on the CMP statute, an Administrative Law Judge, in an appeal of a CMP levied by the OIG, would not be bound by the OIG's interpretation of the CMP statute. See 42 C.F.R. § 1005.4(c) (1) (stating that ALJ does not have authority to refuse to follow federal regulations). Likewise, the agency would not be entitled to *Chevron* deference in a judicial appeal of a CMP. See *Christensen v. Harris County*, 529 U.S. 576 (2000); *United States v. Mead Corp.*, 533 U.S. 218 (2001).

[22] OIG Special Advisory Bulletin on "Gainsharing Arrangements and CMPs for Hospital Payments to Physicians to Reduce or Limit Services to Beneficiaries" (July 1999) (internal footnotes omitted), 64 Fed. Reg. 37985-86 (July 14, 1999), available at: <http://www.oig.hhs.gov/fraud/docs/alertsandbulletins/gainsh.htm>.

[23] In the 1999 alert, available at http://www.oig.hhs.gov/fraud/fraudalerts_bulletins.asp, the OIG stated that the 1994 proposed rule "articulated a categorical prohibition on hospital payments to physicians that are based on reductions in costs for treatment of fee-for-service patients *under the physicians' direct care.*" (Emphasis in the original.) The alert interpreted the

proposed rule as dividing the universe of gainsharing arrangements into two groups—those that involved payments for direct care and those that did not. The alert further indicated that *only* the latter category was potentially permissible under the CMP statute and that language in the proposed rule concerning the need for a case-by-case approach pertained *only* to the latter category. The 1999 alert’s view of the proposed rule may be mostly correct, but the proposed rule is at least a little ambiguous on this point. See 59 Fed. Reg. 61571, 61573 (Dec. 1, 1994) (“We believe, for example, there may be certain types of hospital incentive plans to physicians, *such as* those designated to reward the timely review and completion of medical records which do not impact on direct patient care responsibilities *or* do not affect referral patterns”) (emphasis added).

[24] See *Hearing on Gainsharing Before the Subcomm. on Health of the H. Comm. on Ways and Means*, 109th Cong. 8 (Oct. 7, 2005) (prepared statement of Lewis Morris, Chief Counsel to the Inspector General, U.S. Department of Health and Human Services) (“Any hospital gainsharing plan that encourages physicians, through direct or indirect payments, to reduce or limit clinical services violates the CMP [statute]. The payment need not be tied to an actual reduction in care or to a reduction in medically necessary services[.]”). A copy of the testimony is also *available at* <http://www.oig.hhs.gov/testimony/docs/2005/Gainsharing10-07-05.pdf>.

[25] OIG Special Advisory Bulletin, *supra* note 22.

[26] Included in the total is Advisory Opinion 08-16 (Oct. 7,

2008), which involved a pay-for-performance arrangement.

[27] Testimony of Lewis Morris, Chief Counsel to the Inspector General, House Committee on Ways and Means, Subcommittee on Health (Oct. 2007), *available at* <http://www.oig.hhs.gov/testimony/docs/2005/Gainsharing10-07-05.pdf>.

[28] OIG Advisory Opinion No. 08-15 (2008).

[29] *See, e.g.*, OIG Advisory Opinion No. 08-21, at 10 (Nov. 25, 2008) (“[t]he Arrangement might induce physicians to reduce or limit the then-current medical practice at the hospital. We recognize that the then-current medical practice [at the subject hospital] may have involved care that exceeded the requirements of medical necessity. However, whether the current medical practice reflects necessity or prudence is irrelevant for purposes of the CMP [statute].”); OIG Advisory Opinion No. 05-1, at 8 (Jan. 28, 2005) (same). OIG Advisory Opinion No. 01-1, at 8 (2001) (same). The OIG thus equates the statutory prohibition on paying physicians to reduce or limit at in services with paying physicians to effect a reduction or limitation in the particular medical practice at a particular hospital. It is the author’s understanding that OIG believes that the CMP statute does not prohibit hospitals from mandating a change in their particular medical practices, such as mandating that a particular supply or device be used, but only that, in the absence of such a mandate, it prevents paying physicians for using such supply or device.

[30] *See, e.g.*, OIG Advisory Opinion No. 08-21, at 10 (Nov.

25, 2008); OIG Advisory Opinion No. 07-22, at 9-10 (Dec. 28, 2008); OIG Advisory Opinion No. 05-06, at 8 (Feb. 18, 2005).

[31] 42 U.S.C. § 1320a-7a(b)(1). This text from the 1986 enactment was left undisturbed by the 1990 amendment.

[32] OIG Special Advisory Bulletin, *supra* note 22.

[33] See, e.g., Webster's New Collegiate Dictionary (2b "help, use benefit;" 2c "contribution to the welfare of others;" 4a "a helpful act;" 4b "useful labor"); American Heritage Dictionary of the English Language (4th Ed. 2000) (8b ("act of assistance or benefit")); Dorland's Medical Dictionary ("the performance of work for others or the performance of an action for the benefit of others").

[34] In a recent advisory opinion, the OIG found that even tying physician compensation to achieving quality measures that have been endorsed by CMS and the Joint Commission, as described in the Specifications Manual for National Hospital Inpatient Quality Measures (*available at* <http://www.qualitynet.org>) can implicate the CMP statute. OIG Advisory Opinion 08-16 (Oct. 7, 2008).

[35] See U.S. Government Accountability Office, "Physician Incentive Payments by Hospitals Could Lead to Abuse," HRD-86-103, at 14-20, 22-25 (July 1986), *available at*: <http://archive.gao.gov/d4t4/130544.pdf>.

[36] The GAO Report stated:

If only unnecessary services are forgone, incentive

payments could be viewed as a form of profit sharing. If necessary services are forgone, it would constitute a threat to the health of Medicare beneficiaries.

Chapter 3 discusses what kinds of physician incentive plan features could provide too strong an incentive to physicians *to forgo needed services and how the law could be changed to prohibit including such features in physician incentive plans.* (Emphasis added.)

Id. at 12.

[37] See H.R. Conf. Rep. No. 99-1012 at 306-08 (1986), reprinted in 1986 U.S.C.C.A.N. 3868, 3951-53; H.R. Rep. No. 99-727 at 444-45, 1986 U.S.C.C.A.N. at 3841-42.

[38] 42 U.S.C. § 1320a-7a(b)(1).

[39] See, e.g., *Sullivan v. Finkelstein*, 496 U.S. 617, 631-32 (1990) (Scalia, J., concurring) (“The legislative history of a statute is the history of its consideration and enactment. ‘Subsequent legislative history’—which presumably means the *post*-enactment history of a statute’s consideration and enactment—is a contradiction in terms. The phrase is used to smuggle into judicial consideration legislators’ expressions *not* of what a bill currently under consideration means (which, the theory goes, reflects what their colleagues understood they were voting for), but of what a law *previously enacted* means. . . . In my opinion, the views of a legislator concerning a statute already enacted are entitled to no more weight than the views of a judge concerning a statute not yet passed. . . . Arguments based on subsequent

legislative history, like arguments based on antecedent futurity, should not be taken seriously, not even in a footnote."); *U.S. v. Price*, 361 U.S. 304, 313 (1960) (holding that "the views of a subsequent Congress form a hazardous basis for inferring the intent of an earlier one"); see also *Cobell v. Norton*, 428 F.3d 1070, 1075 (D.C. Cir. 2005) ("[P]ost-enactment legislative history is not only oxymoronic but inherently entitled to little weight.").

[40] OBRA '90, Pub. L. No. 101-508, §§ 4204(a) and 4731, 104 Stat. 1388 (1990). Section 4204(a) added § 1876(i)(8) of the Act. Subparagraph (A) of section 1876(i)(8) sets forth the requirements of managed care incentive plans:

(A) Each contract with an eligible organization under this section shall provide that the organization may not operate any physician incentive plan (as defined in subparagraph (B)) unless the following requirements are met:

(i) No specific payment is made directly or indirectly under the plan to a physician or physician group as an inducement to reduce or limit medically necessary services provided with respect to a specific individual enrolled with the organization.

(ii) If the plan places a physician or physician group at substantial financial risk (as determined by the Secretary) for services not provided by the physician or physician group, the organization--

(I) provides stop-loss protection for the physician or

group that is adequate and appropriate, based on standards developed by the Secretary that take into account the number of physicians placed at such substantial financial risk in the group or under the plan and the number of individuals enrolled with the organization who receive services from the physician or the physician group, and

(II) conducts periodic surveys of both individuals enrolled and individuals previously enrolled with the organization to determine the degree of access of such individuals to services provided by the organization and satisfaction with the quality of such services.

(iii) The organization provides the Secretary with descriptive information regarding the plan, sufficient to permit the Secretary to determine whether the plan is in compliance with the requirements of this subparagraph.

[41] [OIG Special Advisory Bulletin](#), *supra* note 22.

[42] *Id.*

[43] In fact, except for a single reference, the OBRA '90 Conference report does not even acknowledge that the statute applies to hospitals; rather, its focus is on managed care plans. See H.R. Conf. Rep. No. 101-964 at ____, *reprinted in* 1990 U.S.C.C.A.N. 2374, 2483; *id.* at ____, 1990 U.S.C.C.A.N. at 2484; *id.* at ____, 1990 U.S.C.C.A.N. at 2487; *id.* at ____, 1990 U.S.C.C.A.N. at 2583. Likewise, the OBRA '89 Conference Report does not acknowledge that the

CMP statute applies to hospitals. H.R. Conf. Rep. No. 101-386 at 839-843, *reprinted in* 1989 U.S.C.C.A.N. 3018, 3442-46. Except for one passing reference, the OBRA '89 House Report also omits any mention of the CMP statute as applying to hospitals. See H.R. Rep. No. 101-247 at 366, 926, 1036-37, *reprinted in* 1989 U.S.C.C.A.N. 1906, 2092, 2397, 2507-8. It should be noted that in the Omnibus Budget Reconciliation Act of 1993, Pub. L. No. 103-66, §13562, 107 Stat. 312, 600-01 (1993), Congress amended the physician self-referral statute, section 1877 of the Act (42 U.S.C. § 1395nn), to provide an exception to the general prohibition on self-referral in the case of physician incentive plans, but neither the text of the exception nor its legislative history shed any light on the issues discussed in this article. See section 1877(e)(3)(B) of the Act (42 U.S.C. § 1395nn(e)(3)(B)); H.R. Conf. Rep. No. 103-213 at 815, 1993 U.S.C.C.A.N. 1088, 1504.

[44] See §§ 1102(a) and 1871(a) of the Act, as codified at 42 U.S.C. §§ 1302 and 1395hh.

[45] Blanchard, Jr. Jerred G., Hooker, Kenneth L., and Vogel, Gary R., *Underwater Assets And Insolvent Corporations: Reflections On Treasury's Recently Proposed Regulations And Related Matters*, 59 Tax Law. 107, 199 (2005).

[46] As noted above, it appears that at the time OBRA '90 was enacted, the OIG had not formulated its interpretation that the CMP statute forbids paying physicians to not provide medically unnecessary services or its interpretation that the statute prohibits paying physicians to use one supply

or device rather than its clinical equivalent.

[47] Courts have rejected the notion that an agency is prohibited from changing its interpretation in several cases brought by taxpayers. In *Helvering v. Wilshire Oil Co.*, the Supreme Court stated:

The oft-repeated statement that administrative construction receives legislative approval by reenactment of a statutory provision, without material change covers the situation where the validity of administrative action standing by itself may be dubious or where ambiguities in a statute or rules are resolved by reference to administrative practice prior to reenactment of a statute; and where it does not appear that the rule or practice has been changed by the administrative agency through exercise of its continuing rule-making power. It does not mean that a regulation interpreting a provision of one act becomes frozen into another act merely by reenactment of that provision, so that that administrative interpretation cannot be changed prospectively through exercise of appropriate rule-making powers. The contrary conclusion would not only drastically curtail the scope and materially impair the flexibility of administrative action; it would produce a most awkward situation. Outstanding regulations which had survived one Act could be changed only after a pre-view by the Congress.

308 U.S. 90, 100-01 (1939) (citations omitted). Two years later, in *Helvering v. Reynolds*, the Court stated: “[The

reenactment doctrine] is no more than an aid in statutory construction. While it is useful at times in resolving statutory ambiguities, it does not mean that the prior construction has become so imbedded in the law that only Congress can effect a change. It gives way before changes in the prior rule or practice through exercise by the administrative agency of its continuing rulemaking power." 313 U.S. 428, 432 (1941) (citations omitted). *See also Comm'r of Internal Revenue v. P.G. Lake, Inc.*, 356 U.S. 260, 266 n.5 (1958) (prior administrative action always subject to change through exercise by administrative agency of its continuing rulemaking power); *McCoy v. United States*, 802 F.2d 762, 766 (4th Cir. 1986) ("Congressional reenactment of a statutory provision that is subject to a longstanding administrative interpretation of which Congress was aware at the time of reenactment may well create a presumption that Congress has accepted that interpretation as a permissible one; it does not preclude the administrative agency, in the exercise of its rulemaking authority, from later adopting some other reasonable and lawful interpretation of the statute."); 2B Norman J. Singer & J.D. Shambie Singer, *Sutherland Statutes and Statutory Construction* § 49:9 (7th ed.) ("The [legislative reenactment] doctrine has been limited to the extent that a later administrative interpretation can prospectively alter a former reenacted construction.").

[48] *See, e.g., Young v. Comty. Nutrition Inst.*, 476 U.S. 974, 983 (1986) ("[C]ongressional failure to revise or repeal the agency's interpretation is persuasive evidence that the interpretation is the one intended by Congress." (quoting

NLRB v. Bell Aerospace, Co., 416 U.S. 267, 275 (1974))).

[49] See, e.g., *Jewish Hosp. v. Sec'y of Health and Human Servs*, 19 F.3d 270, 286 (6th Cir. 1994).

[50] In *Rapanos v. United States*, the Supreme Court stated:

Although we have recognized congressional acquiescence to administrative interpretations of a statute in some situations, we have done so with extreme care. Failed legislative proposals are a particularly dangerous ground on which to rest an interpretation of a prior statute. . . .

Congress takes no governmental action except by legislation. What the dissent refers to as “Congress’ deliberate acquiescence” should more appropriately be called Congress’s failure to express any opinion. We have no idea whether the Members’ failure to act in 1977 was attributable to their belief that the Corps’ regulations were correct, or rather to their belief that the courts would eliminate any excesses, or indeed simply to their unwillingness to confront the environmental lobby.

547 U.S. 715, 749 (2006) (internal citations, quotations marks, and formatting omitted).

[51] In *Rust v. Sullivan*, the Supreme Court noted that:

In *Chevron*, we held that a revised interpretation deserves deference because [a]n initial agency

interpretation is not instantly carved in stone and the agency, to engage in informed rulemaking, must consider varying interpretations and the wisdom of its policy on a continuing basis. An agency is not required to establish rules of conduct to last forever, but rather must be given ample latitude to adapt [its] rules and policies to the demands of changing circumstances.

500 U.S. 173, 186-87 (1991) (citations and quotation marks omitted). In an earlier case, the Court observed that “[regulatory agencies] are neither required nor supposed to regulate the present and the future within the inflexible limits of yesterday.” *American Trucking Ass’ns., Inc. v. Atchison, Topeka & Santa Fe Ry. Co.*, 387 U.S. 397, 416 (1967).

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