 January 16, 2013

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Dear Mr. Kass:

 For the reasons given below, the Department does not presently intend to challenge the gainsharing program that the Greater New York Hospital Association (“GNYHA”) proposed in its August 13, 2012, business review request (“Request”) to the Department.

**A. Background**

 GNYHA represents that it is a trade association of 250 hospitals and continuing care facilities in New York and several nearby states. Its members range from community hospitals to sophisticated academic medical centers. GNYHA seeks a business review regarding a voluntary gainsharing program that it plans to make available to the 100 hospitals that are its New York members.[[1]](#footnote-1)

According to GNYHA, “gainsharing programs are designed to encourage physicians to take into account their use of hospital resources in their decision-making process and to reward them by providing them with a portion or ‘share’ of the savings or ‘gain’ that results from more efficient use of those resources.” GNYHA states that its proposed program is “designed to provide a framework by which participating hospitals can measure physician performance against certain benchmarks and award bonuses to physicians for improvements in quality and efficiency.” Under GNYHA’s proposal, “physicians who meet hospital-specific quality standards while reducing costs could be compensated financially with a share of the savings realized by the participating hospital.”[[2]](#footnote-2)

GNYHA asserts that its proposal is based upon gainsharing demonstration programs that Medicare has created “and incorporates the same system of safeguards employed in those programs.”[[3]](#footnote-3) Indeed, GNYHA represents that the primary difference between those programs and its program is that the former applies only to Medicare, whereas GNYHA’s Program will apply only to commercial health insurance and Medicaid and Medicare managed care products.[[4]](#footnote-4) GNYHA also represents that its proposed gainsharing program “requires significant programmatic support and infrastructure that hospitals generally can not afford to provide on their own.”[[5]](#footnote-5)

Under GNYHA’s program “participating hospitals would rely on case-level data that is already tracked for public reporting purposes.” This data would be used by GNYHA and Applied Medical Software, Inc. (“AMS”) “to compute the costs associated with specific inpatient services performed by specific physicians.” (GNYHA states that AMS “provides the methodology, analysis, and technical support necessary for [Medicare] and hospitals participating in the [Medicare] demonstration programs.”) If a particular physician’s costs for a specific service “go down or remain significantly low while maintaining or improving quality of care (as measured by the individual institution), that physician may be compensated with a portion of the resulting hospital savings.” Each hospital would “determine whether and to what extent to compensate these physicians.”[[6]](#footnote-6)

Specifically, GNYHA’s represents that its gainsharing program will work as follows:

First, hospitals wishing to participate in the program will provide GNYHA with publicly available data about their costs for various procedures and treatments, which GNYHA in turn will convey to AMS. Each of those hospitals will submit quarterly to AMS, via GNYHA, patient discharge data that “it and every other New York State hospital regularly maintains and submits to the State of New York for ongoing public reporting purposes.” The patient discharge data will use the All Patient Refined Diagnosis Related Group (“APR-DRG”) that Medicare has designated for the specific treatment or procedure.[[7]](#footnote-7)

Second, from this “publicly available, historical data,” AMS will develop Best Practice Norms for each APR-DRG. It will do so by determining “the 25th percentile of the cost” among all hospitals in New York State for the particular APR-DRG.[[8]](#footnote-8) The data that AMS will use to generate the Best Practice Norms will be (a) “at least three months old,” (b) supplied by “at least five providers” with “no individual provider’s data represent[ing] more than 25% on a weighted basis of that statistic,” and (c) “sufficiently aggregated such that it would not allow recipients to identify the prices charged or compensation paid by any particular provider.” The Best Practice Norm for any APR-DRG “will be common across hospitals.”[[9]](#footnote-9)

Third, for each participating hospital, AMS will use the compiled cost data to measure individual physician performance relative to the Best Practice Norm for the APR-DRG in question. AMS will not share this data with anyone other than the particular hospital, and any hospital participating in the GNYHA program will not share this data with another hospital.[[10]](#footnote-10)

Fourth, each participating hospital will “independently and unilaterally” cap the amount of money that the hospital will make “available for incentive payments to its participating physicians.” This cap, GNYHA explains, “is the amount of money” that a hospital makes “available for incentive payments to its participating physicians.” This information “would not be shared with other hospitals.” While hospitals “have substantial flexibility in setting this cap,” GNYHA, to protect against fraud and abuse concerns,[[11]](#footnote-11) “reserves the right to exclude any hospital from the program, if in GNYHA’s unilateral opinion and sole discretion, the hospital’s proposed cap does not comply with applicable laws and regulations.”[[12]](#footnote-12)

In particular, “each participating hospital must include a cap on the amount of the incentive payments that each physician can receive under the program,” and this cap “must be specified as a percentage of Medicare Part B fees.” It also “must be supported by a legal opinion provided by the participating hospital’s legal counsel.” The opinion is required to “ensure[ ] that each participating hospital, the program, and GNYHA are, to the best of their ability based on existing Federal guidance, acting in compliance with applicable laws and regulations for the purposes of the program,” including “the Civil Monetary Penalties law, 42 U.S.C. § 1320a-7a(b), the physician self-referral or ‘Stark’ law, 42 U.S.C. § 1395nn, and the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b).” These laws, GNYHA explains, “require that health care providers participating in the Medicare and Medicaid program neither make nor accept payments for the purposes of limiting medically necessary care or referring patients improperly for pecuniary gain.”[[13]](#footnote-13)

Fifth, once the hospital sets its cap, “it must then unilaterally and independently allocate the total incentive amount across two types of incentives.” Both types will focus on the performance of a physician on individual cases vis-à-vis the specific APR-DRG for which the patient was admitted. The Performance Incentive will “compare[ ] a physician’s performance to his/her peers” based on the Best Practice Norm. The Improvement Incentive will “compare[ ] a physician’s performance to his/her own performance over time.” The allocation between these two Incentives, GNYHA states, will contribute considerably to “significant variation among the actual incentive payments made under this Program.”[[14]](#footnote-14)

Sixth, “once the differing incentives are calculated, they are next conditioned on the physician’s satisfaction of quality metrics that are established and modified by each participating hospital.” While participating hospitals “must, at a minimum, measure physician performance against a basic set of quality metrics established by [Medicare] demonstration programs,” “ultimately,” there is “substantial variation in the types of metrics that each hospital can employ, reflecting each hospital’s individual need and priorities.”[[15]](#footnote-15)

Seventh, GYNHA is contracting with a health care consultant to provide a fair market value analysis “to ensure that the hospital and its physicians have actually taken concrete steps to justify the award of incentive payments.” GNYHA represents that this analysis “merely provides a back-stop to ensure that the participating hospitals are providing compensation for actual efforts to improve efficiency, and not compensation for reducing care or for steering patients in violation of the relevant fraud and abuse statutes, including the Physician Self-Referral (‘Stark’) law, 24 U.S.C. §1395nn.” Each participating hospital will “receive an institution-specific report, with a unique, defined ranged of [fair market value] for the identified conduct at the individual facility.” This information “will not be shared among the participating hospitals.”[[16]](#footnote-16)

GNYHA emphasizes that “nothing in GNYHA’s by-laws or elsewhere [will] require its member hospitals to participate in the Program or to use this Program in lieu of other similar programs.” GNYHA also emphasizes that of the roughly 100 individual New York State hospitals in GNYHA’s membership, only 11 members have registered for the Program. Each of those hospitals “would implement the Program with its own variations to address the individual hospital’s specific needs.”[[17]](#footnote-17)

GNYHA asserts that a gainsharing program such as it is proposing “necessarily must have certain caps and safeguards against fraud and abuse to protect patients against any potential diminution in medically necessary care and other improper decisions.”[[18]](#footnote-18) Exhibits that GNYHA attached to its business review request[[19]](#footnote-19) indicate that both of the two major operative hospital gainsharing demonstration projects that Medicare has had to date[[20]](#footnote-20) had provisions limiting the incentive payments participating hospitals could make to individual physicians to “25 percent of the amount that is normally paid to physicians for cases in the gainsharing demonstration.”[[21]](#footnote-21)

GNYHA states that the program will be open only to its New York member hospitals at this time because “New York fraud and abuse laws do not prohibit the type of program we are proposing.”[[22]](#footnote-22) According to GNYHA, “Because the consequences of getting the legal analysis wrong is significant, participants and GNYHA itself need as high a degree of comfort as possible that the program, as structured, will pass muster under both Federal and State law.”[[23]](#footnote-23)

**B. Analysis**

The Request raises two antitrust issues: Whether it constitutes (1) a horizontal agreement among competing hospitals about compensation levels for physicians or (2) an information exchange among hospitals that would facilitate anticompetitive coordination among hospitals to limit physician compensation. Based on the representations that GNYHA makes in its business review request, GNYHA’s proposed gainsharing program appears unlikely to cause these or other anticompetitive effects.

 **1. No Agreement About Compensation Levels**

GNYHA represents that its proposed gainsharing program does not “involve any agreement, coordination, or discussion concerning the prices that participating hospitals or physicians charge for their services” or “inhibit competition in any way.” GNYHA emphasizes that “Each hospital … independently and unilaterally determines a hospital-specific [physician incentive payments] cap.” Indeed, GNYHA states, “hospitals that voluntarily elect to participate in the Program [are] not obligated to make *any* incentive payments (and one hospital has indicated its intention not to make such payments)” (italics in original).[[24]](#footnote-24)

The Program, however, does provide that, “For the sole purpose of ensuring compliance with applicable laws and regulations, GNYHA reserves the right to exclude any hospital from the program, if in GNYHA’s unilateral opinion and sole discretion, the hospital’s proposed cap does not comply with applicable laws and regulations.”[[25]](#footnote-25) It also provides that a fair market value analysis “will be conducted to ensure that the hospital and its physicians have actually taken concrete steps to justify the award of incentive payments.”[[26]](#footnote-26)

As GNYHA states, these two provisions appear reasonably necessary for the program to be effective because they are designed to prevent fraud and abuse, reasonably ancillary to the overall legitimate purposes of the Program, and the least restrictive means possible to achieve the Program’s purposes. As GNYHA states, these provisions appear to be consistent with various Medicare hospital gainsharing demonstration programs, which include caps for Medicare Part B fees.[[27]](#footnote-27)

According to GNYHA’s representations, the provisions are necessary because, without them, “no hospital would participate in the Program, since doing so would risk exposing them to significant liability under applicable state and/or Federal law.” Also compelling is GNYHA’s representation that “each of the safeguards included in the Program are based on demonstrations programs established in conjunction with, and guidance issued by [Medicare].”[[28]](#footnote-28)

In addition, the wide variation in cost structures among hospitals would appear to make it difficult for GNYHA to develop, or maintain, an agreement among hospitals regarding a limit on a physician gainsharing. If, however, GNYHA in practice uses program provisions related to physician payment caps or fair market value analysis to coordinate or standardize hospital payments to physicians, such conduct would be subject to prosecution under the antitrust laws.

**2. No Anticompetitive Information Exchange**

GNYHA contends that its proposed “Program is built on data that is already publicly available” and “will not involve the exchange of *any* competitively sensitive information among the hospitals” (italics in original).[[29]](#footnote-29) It emphasizes that “as part of the Program, we intend to restrict the dissemination of information to non-competitively sensitive cost and benchmark data.”[[30]](#footnote-30) GNYHA also emphasizes that the data that AMS will use to generate the Best Practice Norms that GNYHA will be distributing to participating hospitals will be (a) “at least three months old,” (b) supplied by “at least five providers” with “no individual provider’s data represent[ing] more than 25% on a weighted basis of that statistic,” and (c) “sufficiently aggregated such that it would not allow recipients to identify the prices charged or compensation paid by any particular provider.”[[31]](#footnote-31)

According to GNYHA’s representations, the only information that GNYHA will be sharing among the participating hospitals as a group will be the state-wide Best Practice Norm for each APR-DRG. GNYHA, through AMS, will generate each Best Practice Norm solely upon data that will be at least three months old and supplied by at least five providers, with no individual provider’s data representing more than 25% on a weighted basis of the Norm. The Norm will also be sufficiently aggregated such that it will not allow any of the hospitals receiving the information to identify the prices charged or compensation paid by any particular provider. GNYHA’s proposed sharing of state-wide Best Practice Norms with participating hospitals therefore complies with the antitrust safety-zone requirements of Statement 6 of the Department of Justice’s and Federal Trade Commission’s *Statements of Antitrust Enforcement Policy in Health Care* (1996).[[32]](#footnote-32) In addition, an examination of the sample of reports that AMS will generate for each participating hospital[[33]](#footnote-33) confirms that the data that GNYHA proposes to make available under its gainsharing program will not allow providers to determine what other providers are receiving, paying, or charging. GNYHA’s proposed information sharing program consequently is unlikely to facilitate collusion or otherwise raise competitive concerns.

**C. Conclusion**

 Based on your representations, the Department has no present intention to challenge the formation or operation of the GNYHA’s voluntary hospital gainsharing program under the antitrust laws. This letter expresses the Department’s current enforcement intentions and is predicated on the accuracy of the information and assertions that you have presented to us in your August 13, 2012, letter to the Department.

 The Department’s present intention is predicated upon (1) the program participants’ refraining from exchanging competitively sensitive information and (2) program provisions related to physician payment caps and fair market value analysis being reasonably necessary to further the procompetitive purposes of the gainsharing program. If GNYHA uses those provisions as a pretense for coordinating hospital payments to physicians, such conduct would be subject to prosecution under the antitrust laws.

 This statement is made in accordance with the Department’s Business Review Procedure, 28 C.F.R. §50.6. Pursuant to its terms, your business review request and this letter will be made publicly available immediately, and any supporting data will be made publicly available within thirty (30) days of the date of this letter, unless you request that any part of the material be withheld in accordance with Paragraph 10(c) of the Business Review Procedure.

 Sincerely,

 William J. Baer

1. Request at 2-3. [↑](#footnote-ref-1)
2. Request at 1 and 5. [↑](#footnote-ref-2)
3. Request at 5. [↑](#footnote-ref-3)
4. Request at 5, n.1. [↑](#footnote-ref-4)
5. Request at 1. [↑](#footnote-ref-5)
6. Request at 5. [↑](#footnote-ref-6)
7. Request at 6 and 9-10. [↑](#footnote-ref-7)
8. Request at 6. That is, 25 percent of all instances of a given procedure or treatment that were performed in New York State cost less than the Best Practice Norm; 75 percent of all instances of that procedure or treatment performed in New York State cost at least as much as the Best Practice Norm. [↑](#footnote-ref-8)
9. Request at 6 and 7. [↑](#footnote-ref-9)
10. Request at 6. [↑](#footnote-ref-10)
11. This letter does not address whether the proposed program complies with fraud and abuse laws and regulations. [↑](#footnote-ref-11)
12. Request at 6, 7, and 10. [↑](#footnote-ref-12)
13. Request at 2. [↑](#footnote-ref-13)
14. Request at 7-9. [↑](#footnote-ref-14)
15. Request at 8. [↑](#footnote-ref-15)
16. Request at 9. [↑](#footnote-ref-16)
17. Request at 1 and 2 and January 11, 2013, e-mail to the Department. [↑](#footnote-ref-17)
18. Request at 5. [↑](#footnote-ref-18)
19. Exhibits 6 and 7 [↑](#footnote-ref-19)
20. The Section 5007 of the Debt Reduction Act of 2005 Medicare Hospital Gainsharing Demonstration (“DRA 5007”) and the Physician-Hospital Collaboration Demonstration [↑](#footnote-ref-20)
21. Exhibit 6 (DRA 5007 Solicitation, *available* at http://www.cms.hhs.gov/Medicare/Demonstration-Projects/DemoProjectsEvalRpts/Downloads/DRA5007\_Solicitation.pdf ) at 4, Exhibit 7 (Physician-Hospital Collaboration Demonstration Solicitation, *available* at http://www.cms.gov/Medicare/Demonstration-Projects/DemoProjectsEvalRpts/downloads//PHCD\_646\_Solicitation.pdf), at 6. [↑](#footnote-ref-21)
22. Request at 3. [↑](#footnote-ref-22)
23. Request at 12. [↑](#footnote-ref-23)
24. Request at 3, 6, and 14. A hospital participating in a gainsharing program, but not making any incentive payments, would simply provide individual physicians data regarding how that physician’s costs for any given patient compared to the appropriate treatment or procedure Best Practice Norm. *Id*. at 7. [↑](#footnote-ref-24)
25. Request at 2. [↑](#footnote-ref-25)
26. Request at 9. [↑](#footnote-ref-26)
27. Request at 15. [↑](#footnote-ref-27)
28. Request at 3. [↑](#footnote-ref-28)
29. Request at 1. [↑](#footnote-ref-29)
30. Request at 11. [↑](#footnote-ref-30)
31. Request at 6. [↑](#footnote-ref-31)
32. *Available at* http://www.usdoj.gov/atr/public/guidelines/1791.htm. [↑](#footnote-ref-32)
33. Exhibit 5 [↑](#footnote-ref-33)