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Via Courier

Office of the Assistant Attorney General
Antitrust Division
Department of Justice
Main Justice Building
Room 3109
950 Pennsylvania Ave., N.W.
Washington, DC 20530

Re: *Greater New York Hospital Association Proposal*

Dear Mr. Wayland:

The Greater New York Hospital Association (GNYHA) is writing to request a business review letter concerning its plan to establish a voluntary program for its hospital membership.

The Program, which will be administered by GNYHA and Applied Medical Software, Inc. (AMS), 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. As described in more detail below, 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.

The GNYHA/AMS Program requires significant programmatic support and infrastructure that hospitals generally can not afford to provide on their own, due to the substantial costs and burdens of establishing and implementing such a system. While such third-party assistance is required, the Program will not involve the exchange of *any* competitively sensitive information among the hospitals. Indeed, the Program is built on data that is already publicly available.

The Program also does not require agreement among any hospital to either participate in the Program or to award (or refrain from awarding) any bonuses, through this Program or otherwise. Rather, the Program itself is being offered unilaterally by GNYHA/AMS as a service to help hospitals incentivize their physicians to actively engage in improving the quality and efficiency of the care they provide, making the facility more attractive to patients and payors in the process. Notably, nothing in GNYHA's by-laws or elsewhere require its member hospitals to participate in the Program or to use this Program in lieu of other similar programs, either developed internally or offered by another third-party. Put simply, because the Program does not require the agreement or cooperation of competing hospitals, the Program is no different than any other information service or consultancy project unilaterally offered by a third-party.

Tellingly, of the roughly 100 individual New York State hospitals in GNYHA's membership, only the following eight members have registered for the program: Bronx Lebanon Hospital, Lutheran Medical Center, NYU Langone Medical Center, Kingsbrook Jewish Medical Center, New York Methodist Hospital, St. Francis Hospital; Kaleida Health., and Montefiore Medical Center. Each of these hospitals would implement the Program with its own variations to address the individual hospital's specific needs. For example, Bronx Lebanon Hospital does not intend to make payments to its participating physicians, and Montefiore is interested in establishing its own best practices norms based on only academic medical centers in New York state, rather than a norm based on all New York State hospitals. This fact alone not only demonstrates the unilateral nature of the Program, but it also precludes there being any anticompetitive effect within a well-defined relevant antitrust market.

While we believe the Program is inherently unilateral, it is also entirely procompetitive and a prime illustration of "the use of significant financial incentives to achieve specific-cost containment goals" for which the Agencies have previously expressed substantial support. The Program addresses payors' concerns that physicians lack any meaningful incentive to utilize hospital resources efficiently, which ultimately increases costs and reduces quality of care. For example, physicians who engage in more efficient use of hospital services will both reduce payor costs and benefit patients.

The Program, being both unilateral and procompetitive, should not raise any antitrust concerns. Nevertheless, we are seeking a business review letter out of abundance of caution. In particular, in order to function properly and to comply with applicable laws regarding fraud and abuse, the Program contains a number of ancillary – but critically important – safeguards, which effectively cap the amount of incentive payments calculated under the Program.

Most significantly, each participating hospital must include a cap on the amount of the incentive payments that each physician can receive under the program. This cap must be specified as a percentage of Medicare Part B fees, and this cap must be supported by a legal opinion provided by the participating hospital's legal counsel. This ensures 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. Such laws and regulations, discussed in greater detail below, include the following: the Civil Monetary Penalties law, *42 USC 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)*. In general, these 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. These legal restrictions are in place to protect both patients and the Medicare and Medicaid program resources, and the program is structured to eliminate the risk of improper payments being made in violation of these laws. 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.

Without the Program's safeguards, no hospital would participate in the Program, since doing so would risk exposing them to significant liability under applicable state and/or Federal law. Most important, each of the safeguards included in the Program are based on demonstration programs established in conjunction with, and guidance issued by, the Centers for Medicare & Medicaid Services (CMS). Because hospitals will need to ensure that their programs do not unnecessarily expose them to legal risk, even if the hospitals individually developed their own programs, they would necessarily have to impose essentially the same safeguards in order to avoid liability.

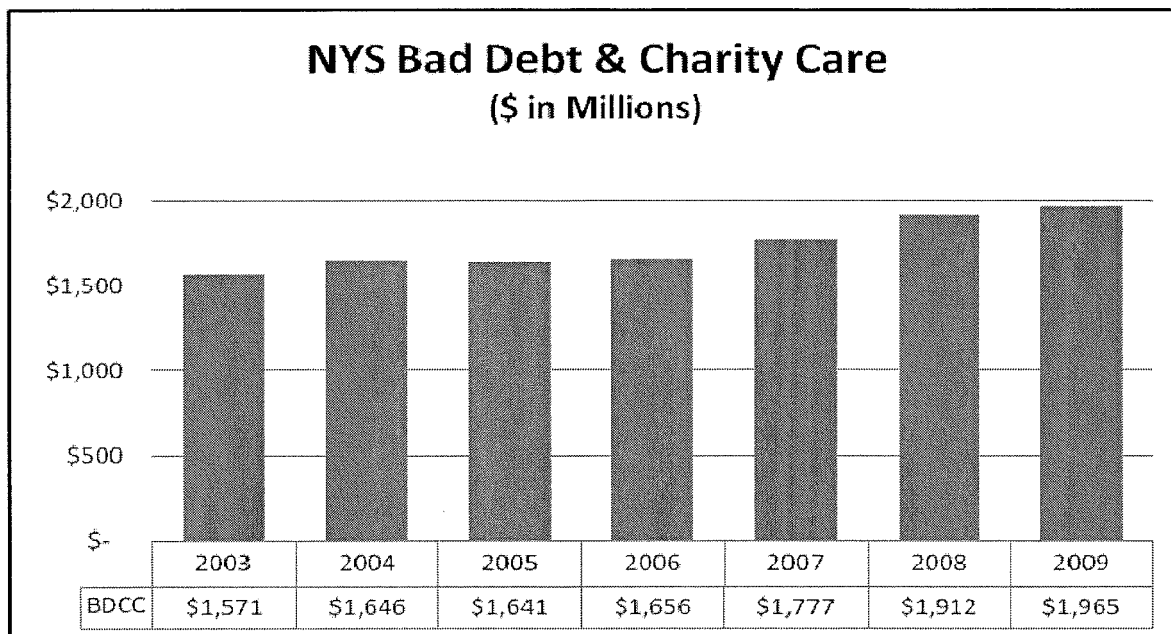
The Program's safeguards are not only ancillary, they can have no anticompetitive effect. The Program benefits payors and patients because it is designed to reduce costs and improve the quality of care provided. The Program also benefits physicians because it allows them to earn additional revenues within the bounds of fraud and abuse restrictions by taking simple steps to improve their efficiency while maintaining or improving quality. Ultimately the Program promotes efficiency and thus fosters competition in the market.

Nor will the Program result in, or encourage, any uniformity among hospitals concerning incentive payments under the Program. Not only are hospitals that voluntarily elect to participate in the Program not obligated to make *any* incentive payments (and one hospital has indicated its intention not to make such payments), the actual incentive payments that each hospital will make to its participating physicians are based on a variety of factors, including hospital-specific quality and performance metrics within the Program framework. This, coupled with each hospital's underlying costs and the specifics of each case, means that incentive payments will vary across physicians and hospitals. Put simply, a physician doing exactly the same work at two hospitals will likely receive different incentive payments, as a result of the hospital-specific aspects of the Program.

I. Background on GNYHA and Its Members

GNYHA (www.gnyha.org) is a not-for-profit trade association representing roughly 250 not-for-profit hospitals and continuing care facilities, both voluntary and public, in the New York City metropolitan area, throughout New York State, and in New Jersey, Connecticut, and Rhode Island. At this time, only New York State hospitals are participating in the Program at issue. This restriction is due to the differences in controlling state laws; broadly speaking, New York fraud and abuse laws do not prohibit the type of program we are proposing, while that is not necessarily the case in other states.

GNYHA's members range from stand-alone community hospitals to some of the most sophisticated academic medical centers in the country. Many of our members are considered "safety net" hospitals, serving low-income, at-risk patients. For the average New York State hospital, roughly 65% of their discharges are Medicare or Medicaid patients. For hospitals located in New York City, this percentage is even higher, at about 69%. Further, our hospitals routinely provide a large amount of uncompensated care to individuals without any form of coverage but who nonetheless require extensive treatment. As the chart below indicates, the New York State Department of Health has found hospitals' bad debt and charity care costs – the expenditures that hospitals make to treat low-income patients without health insurance – have risen consistently during this decade.



Source: New York State Department of Health.

Accordingly, health providers in New York are in a precarious financial position. Many New York hospitals have experienced a persistent negative or near break-even margin for most of the past 10 years. They have been impacted by recent State and Federal funding cuts, and they will likely be subject to additional Medicare and Medicaid cuts in the future. These hospitals must therefore take innovative steps to improve efficiency so that they may remain financially viable and available to care for our communities.

That is where GNYHA comes in. GNYHA provides a range of services to its members, including a number of quality collaboratives in which participating hospitals work together to share best practices relating to an identified quality of care concern, implement productive operational changes, and track resulting outcome data. The knowledge and experience GNYHA staff members and participating hospitals have gained through our collaboratives will carry over to the Program. Previous and ongoing collaboratives have focused on reducing central line-associated bloodstream infections, eradicating *C. difficile* bacterial infections, enhancing perinatal safety, and preventing sepsis. Like the Program discussed herein, such collaboratives are entirely voluntary and open to interested GNYHA members. They too reduce hospital costs while improving outcomes.

II. Overview of the Program

It is well-known that there are a number of market imperfections in the healthcare industry stemming from the disconnect between the payors (insurers) and recipients (patients) of health care services on the one hand, and those who effectively make the purchasing decision (physicians) on the other. This Program is one way to address this problem.

Medicare, and many non-public third-party payors for health care services, pay for most general acute care hospital services using a “case rate” based methodology, rather than a methodology that pays hospitals based on costs incurred. Each hospital is essentially paid the same amount for any admission with the same diagnosis, even if the actual costs or services

provided vary substantially across admissions. In contrast, physicians are compensated primarily on a fee-for-service basis. Thus, the physician who typically controls the course of a patient's admission and stay in a hospital is not necessarily encouraged to adopt practices that might save, or efficiently use, hospital resources. Put simply, the current Medicare hospital and physician payment systems are at odds and create some conflicting economic incentives.

In an effort to address this problem, CMS has created demonstration "gainsharing" programs. At the most basic level, 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. Of course, the goal of such programs is not to avoid necessary or beneficial treatment options, but rather to eliminate unnecessary costs. Such programs 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.

The Program that GNYHA proposes is based on these CMS demonstration programs, and incorporates the same system of safeguards employed in those programs. Notably, AMS provides the methodology, analysis, and technical support necessary for CMS and hospitals participating in the demonstration programs. The primary difference between those programs and this Program is that the former applies only to Medicare, whereas this Program will only apply to the commercial segment of the population.¹

The parameters of the Program are set forth in the hospital Participation Agreement and the Physician Handbook, the current drafts of which are attached as Exhibits 1 and 2.² Broadly speaking, participating hospitals would rely on case-level data that is already tracked for public reporting purposes. This data would be used by GNYHA and AMS to compute the costs associated with specific inpatient services performed by specific physicians. If, during the course of the Program, the individual physician's costs for such services 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. It will be up to each participating hospital to determine whether and to what extent to compensate these physicians within the Program framework.

In order for this Program to work, there must be some limited standardization. Just as with any information service, there is a necessary methodology that the information service provider – in this case, AMS – uses to crunch the numbers and report results. Specifically, AMS has created a framework that allows hospitals to track performance and measure efficiency on a physician-by-physician basis, based on its prior experience in running the CMS demonstration programs. To be clear, any individual hospital contracting with AMS independently would rely

¹ Note that the term "commercial" here means both the normative commercial insurance market and Medicaid and Medicare managed care products. Due to restrictions established by controlling Federal fraud and abuse laws and regulations, Medicare and Medicaid fee-for-service is excluded from the Program.

² Although we are attaching current drafts of the Participation Agreement and the Physician Handbook, GNYHA is still in the process of finalizing the details of the Program, and thus, these operative documents remain subject to change.

on the same methodology that will be used for the Program, but the implementation of this methodology necessarily differs across hospitals.

In essence, the Program works like this: via GNYHA, each participating hospital provides AMS with the same information that it and every other New York State hospital regularly maintains and submits to the State of New York for ongoing public reporting purposes. This is state-wide patient discharge data that is reported on a quarterly basis and then made publicly available, though neither the initial raw data nor the resulting output is ever shared directly among hospitals participating in the Program by GNYHA or AMS.

Rather, the publicly available, historical data is used by AMS to calculate the Best Practices Norm (BPN) for each specific condition – or All Patient Refined Diagnosis Related Group (APR-DRG)³ – that is reviewed as part of the Program. The BPN is set at the 25th percentile of the cost for each APR-DRG, and AMS then uses the compiled cost data to measure individual physician performance relative to the BPN for the APR-DRG in question.

In order to present physician-specific information to participating hospitals effectively, AMS and GNYHA do provide each hospital with the BPN for each relevant APR-DRG so that the hospitals have a basis for understanding their own individual physician performance numbers as compared against the BPN in question. Again, the BPN is based on all public information, established using historical data for what is referred to as the base year. Currently, the base year is 2009, which was the most recently available data when GNYHA's work on this program began. AMS may update this to a 2010 base year as more recent data becomes publicly available in the coming months. In any event, the data is at least three months old.⁴

Note that there are at least five providers reporting data upon which each disseminated statistic is based, no individual provider's data represents more than 25% on a weighted basis of that statistic, and any information disseminated is sufficiently aggregated such that it would not allow recipients to identify the prices charged or compensation paid by any particular provider. In addition, the information used in this calculation is first collected by New York State and is subsequently used by AMS and GNYHA. Thus, only third parties establish the relevant data benchmarks, not the hospitals themselves. As a result of these conditions, the use of information as part of this Program fully complies with the safe harbor provisions of the Department of Justice's *Health Care Guidelines*.

Each hospital also independently and unilaterally determines a hospital-specific cap (which can be set on an APR-DRG-specific basis), which is the amount of money available for

³ Note that APR-DRGs are used to respond to fraud and abuse concerns, particularly in terms of the "Stark" and Civil Monetary Penalties law discussed in greater detail below. By adjusting for severity of illness, APR-DRGs address the salient fraud concerns and protect patients against the risk of financial incentives yielding improper care. It is significant that each element of the AMS methodology was developed to address Federal regulatory health care concerns.

⁴ Of course, the hospital-specific comparison to this benchmark (which is not shared among hospitals) is based on the same public data. Note that the data set used for the individual hospital analysis may be more recent than the state-wide data by a matter of weeks, as there is a natural lag time between the state-wide data submission and subsequent analysis and public release. This more recent data is also not shared among hospitals under this Program.

incentive payments to its participating physicians. One of the participating hospitals, for example, has indicated that it plans to set its cap at 0%, meaning that it will receive the AMS' calculations concerning its own physicians' performance, but it will not make incentive payments to the physicians based on this information.⁵

Once the hospital sets its cap, it must then unilaterally and independently allocate the total incentive amount across two types of incentives: the Performance Incentive and the Improvement Incentive. The Performance Incentive compares a physician's performance to his/her peers based on the BPN. The Improvement Incentive compares a physician's performance to his/her own performance over time. This allocation is set by the hospital and may change over time, depending on the individual facility's needs. For example, some hospitals with significant opportunities for improvement might allocate the payment at 65% Improvement Incentive and 35% Performance Incentive in order to incentivize physician improvements. Other facilities may decide to allocate 75% or even 100% to the Performance Incentive, choosing to emphasize overall performance.

As this demonstrates, the allocation decision depends on the unique needs of each institution. Moreover, even if each participating hospital were to allocate the incentive payment funds in exactly the same manner, the differences in underlying organizational cost structures would still yield differing amounts of opportunity for improvements across hospitals and thus result in meaningful differences in the resulting incentive payments. No two hospitals are alike in efficiency.

Exhibit 3 sets forth examples of calculations of potential incentive payments over time to one physician performing the same services at two different hospitals. Recall that the BPN for the relevant APR-DRG will be common across hospitals. This is set, as established above, at the 25th percentile of the cost for each APR-DRG based on public, historic, state-wide data. The BPN is thus the basis for our example of differing payments at hypothetical Hospital A and B.

Working off this BPN, there is a potential range of incentive payments based on the participating physician's history of efficiency and potential improvement after the incentive payments have been introduced, as well as the participating hospital's allocation of incentive payments, costs, and use of quality metrics. In each example, at Hospital A, the physician historically shows relatively efficient performance for the APR-DRG in question but goes on to make some improvements in response to the Program's incentive payments. At Hospital B, in contrast, the physician shows relatively inefficient performance for the same APR-DRG in the past but then makes significant improvements when the incentive payments are introduced.

For purposes of Example 1, both hospitals allocate two-thirds of the Year One incentive to Improvement and one-third to Performance. That is, the two hospitals in this hypothetical have elected to structure their incentive payments identically. Nonetheless, the actual costs at each hospital necessarily differ since their underlying cost structures vary. Thus, there is no risk of inappropriate standardization in actual bonus payments.

⁵ While hospitals have substantial flexibility in setting this cap, to protect against fraud and abuse concerns, GNYHA also 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.

In Example 2, the theoretical hospitals behave differently. Hospital A maintains the two-thirds to one-third split between Improvement and Performance, while Hospital B allocates its incentive payments to half Improvement and half Performance. Again, the costs at the hospitals differ, and these differences are maintained in Example 2.

What we see in the attached calculations are relatively simple examples of potential differences in incentive payments. In Example 1, where the physicians are performing the same service and the hospitals have allocated their incentive payments in the same way, the physician payments still differ based only on the hospitals' underlying costs. At Hospital A, the physician would have a total incentive of \$600, while the physician would earn \$1,022 at Hospital B. Example 2 assumes the same hospital costs with different allocations within the incentive payment. Thus, at Hospital A, the physician incentive would remain \$600 (Hospital A stayed at a two-thirds to one-third allocation) while the payment is now \$1,074 at Hospital B, which has shifted its incentive payment to half and half.

In addition, the hospitals further uniquely condition the incentive payments on a set of hospital-specific quality metrics. That is, 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. These metrics not only ensure care quality is maintained or improved as a result of the Program, but they also allow hospitals to incentivize physicians across other objectively-determined dimensions. Participating hospitals must, at a minimum, measure physician performance against a basic set of quality metrics established by CMS demonstration programs. These metrics include mortality and readmissions. In addition, each hospital may then impose hospital-specific quality metrics as a condition for payment. These might include measures of operational efficiencies (*e.g.*, more timely consultations), patient satisfaction, and improved clinical outcomes (*e.g.*, reduced hospital-associated infections), and may include triggers that must be met in order to receive any incentive payment or scales that apply that determine the amount of the base incentive that will actually be paid. Ultimately, there is substantial variation in the types of metrics that each hospital can employ, reflecting each hospital's individual needs and priorities.⁶

To illustrate the range and impact of these quality metrics on the potential incentive payments, we have attached real examples as Exhibit 4 of some of the quality metrics proposed by GNYHA members for use in the potential Program. (The names of the hospitals have been redacted.) Note that the measures themselves vary, as do the targets for satisfaction of the standards and the manner by which the standards are used to condition payments. In Hospital 1's proposed quality measures, a physician that satisfies the "Outcome" measures is entitled to 30% of the total incentive payment, a physician that satisfies the "Process of Care" measures is entitled to 15% of the incentive payment and so on. Hospital 2 approaches the measures differently, allowing partial credit for some improvement even if the physician stays below the established goal for certain measures. Finally, other hospitals will chose a more binary approach; their physicians will not receive any payments unless they satisfy all of the identified quality measures. No partial credit or payment will be provided.

⁶ The metrics used in measuring physician quality are based on information each hospital maintains in the ordinary course of business for regulatory or other reasons. As with all other information under this Program, a hospital's physician-specific quality information will not be shared with other hospitals.

As a result of the requirement that each hospital independently and unilaterally set (i) the amount of the maximum physician payment (subject to its hospital-specific cap), (ii) the allocation between Performance and Improvement Incentives, and (iii) the specific quality metrics that apply, there will be significant variation among the actual incentive payments made under this Program.

While the above describes the basic mechanics of the Program, there are three additional safeguards against fraud and abuse. *First*, after the first year of a given hospital's participation, the incentive payments under this Program would not be calculated unless that hospital showed aggregate physician improvement resulting in savings. This limitation is necessary because, as a result of randomness and natural variation, some physicians would naturally improve or perform better than their peers in some years, and worse in others. The Program is designed to actually improve overall efficiency and so must guard against making payments based solely on statistical flukes.

Second, physicians must be on the hospital's staff for at least one year and have a minimum number of admissions to participate. This safeguard increases the data available on which to base physician-specific payments, and further reduces the risk that physicians would be able to take advantage of short-term statistical flukes that bear no correlation to actual gains in efficiency. Most importantly from a fraud perspective, it ensures that hospitals are not perceived as inappropriately compensating physicians to increase their referrals to that hospital.

Third, A fair market value ("FMV") analysis will be conducted to ensure that the hospital and its physicians have actually taken concrete steps to justify the award of incentive payments. Practical Healthcare Solutions ("PHS") was retained to perform this FMV analysis. Under this FMV analysis, each hospital will identify the specific, non-clinical steps to be taken to improve its performance, and PHS will determine, based on the information provided by the specific hospital and other publicly available information, the FMV of that conduct. Each hospital will then receive an institution-specific report with a unique, defined range of FMV for the identified conduct at the individual facility. This information will not be shared among the participating hospitals, and it cannot result in any coordination among hospitals with respect to incentive payments under the Program. In addition, practically speaking, the FMV is unlikely to have any impact on the actual payments physicians receive under the Program, since the FMV does not factor directly into the way payments are calculated. Instead, the FMV 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, 42 U.S.C. § 1395nn. It is another Program safeguard to promote program integrity. Thus as long as the payments do not exceed the determined FMV for the identified conduct, physician payments will be made according to the AMS methodology described herein.

As discussed, each of these safeguards is limited in scope, necessary to comply with applicable Federal and State laws concerning fraud and abuse, and specifically tailored on guidance provided by CMS.

A. Project Roles and Responsibilities

To effectively implement the Program, each hospital must commit to independently:

- Appoint an implementation team and a Program Coordinator (COO, VP, or other administrative staff).
- Convene a hospital-based quality oversight steering committee including 50% physician representation, administration, finance and other relevant stakeholders. The individual hospital steering committee would be responsible for (i) defining the overall parameters of the hospital program; (ii) determining eligibility requirements; (iii) customizing quality measures; and (iv) reviewing data and tracking quality to determine physician eligibility for each payment period.
- Aggregate and report on a set of quality metrics as determined by the hospital's own steering committee. This information would not be shared with other hospitals.
- Independently determine whether and at what level to offer physician incentive payments within the overall Program framework. This information would not be shared with other hospitals.

In turn, GNYHA would provide support in the following areas:

- Technical Assistance with Data. GNYHA would assist with the collection, aggregation, and normalization of quarterly hospital discharge data. It would help ensure data integrity, including data editing and feedback to hospitals for improved accuracy in future submissions to AMS for the purpose of calculating physician data.
- Implementation Support. GNYHA would provide support for hospital Program Coordinators and implementation teams including training and ongoing technical support. It would also provide on-site implementation assistance, including convening the hospital steering committee and promoting the Program to facilitate its adoption and success.
- Contract with Independent Third Party. GNYHA has contracted with AMS to compute physician incentives, consistent with the methodology, customized independently by each institution within the overall Program framework. In addition, we are contracting with a health care consultant to provide the necessary FMV analysis to ensure that physician payments are within an appropriate range.

III. Information Collection, Aggregation, and Dissemination

In order for the proposed Program to function, it is critical that hospitals have access to accurate information concerning the costs necessary to treat patients with varying illnesses and degrees of severity. Given the differences in medical care costs across the country, this information must be local and community-based. At the same time, there must be sufficient data points to make the calculation of average and benchmark costs statistically meaningful and immune from manipulation, bias, or outliers.

Thus, GNYHA would serve a significant role vis-à-vis the data involved in the Program. Specifically, The Health Economics and Outcomes Research Institute (THEORI), GNYHA's in-house health economics division, would be collecting data directly from each participating hospital and applying it as needed according to AMS methodology, which was discussed above. *See supra.*, at n. 4. GNYHA's central role would reduce hospitals' expenditure of time and money with respect to data collection and allow AMS to serve as an independent entity applying the methodology and performing the necessary calculations. AMS would be an impartial expert, rather than a direct partner with the participating hospitals, and we believe this would yield a more robust result.

In addition, GNYHA's staff and support would enable participating hospitals to achieve efficiencies more consistently and quickly than if each hospital were acting alone. First, quite simply, GNYHA is able to facilitate the development of the Program – contracting with AMS, utilizing the in-house data expertise of THEORI, emphasizing the necessary restrictions of the Program – more quickly than our individual members could on their own. Similarly, GNYHA's in-house data analytic services and knowledge of hospital operations would serve as a resource for members, reducing their investments and implementation delays. Further, GNYHA has financial resources to expend on the necessary start-up fees (*i.e.*, legal and consulting) that our individual members might lack or be reluctant to commit. Participating hospitals are paying a basic fee to GNYHA to cover some operating costs, but GNYHA has assumed the primary financial risk for the Program's start-up.

Compliance with the antitrust laws, of course, is a high priority for GNYHA and its members. Thus, as part of the Program, we intend to restrict the dissemination of information to non-competitively sensitive cost and benchmark data. This data would allow hospitals to compare physician performance relative to the overall market, but it would be sufficiently aggregated to ensure that neither hospitals nor physicians can use this information to determine the prices that any competing hospital or physician charges for medical services. Exhibit 5 provides sample of the reports that AMS would generate for each participating hospital.

Finally, the Program would be transparent. All patients admitted to a hospital would be advised that the hospital compensates physicians to control the cost of care and improve outcomes by, among other things, reducing unnecessary services. Likewise, participating hospitals would be advised to inform the managed care payors with which they participate about the Program.

IV. Overview of Fraud and Abuse Laws and Related Considerations

Though gainsharing programs can serve as effective drivers to promote efficiency and contain costs, they have been limited historically due to significant restrictions imposed by the Federal fraud and abuse provisions of the Civil Monetary Penalties law (CMP), the Physician Self-Referral or “Stark” law, and the Anti-Kickback Statute (AKS). If a program is not structured carefully and exactly, it could appear to violate one of these laws or a state-level counterpart and expose the hospital to significant liability.

We will briefly outline the prohibitions set forth in each of these laws to provide background on the necessary shape of the proposed Program.

- a. Civil Monetary Penalties law. The CMP, 42 USC 1320a-7a(b), prohibits hospital payments to physicians to induce any reductions or limitations of Medicare or Medicaid services to patients. Gainsharing has been interpreted as generating such payments by the Department of Health and Human Services, Office of Inspector General (OIG). However, the OIG has limited such concerns to fee-for-service payments only, rather than managed care payments. Both the OIG's 1999 Special Advisory Bulletin on Gainsharing and the subsequently published "Recent Commentary Distorts HHS IG's Gainsharing Bulletin" explain the risks inherent in a gainsharing program but limit concerns of a CMP violation by a gainsharing arrangement to a Medicare/ Medicaid fee-for-service population, due to separate Federal laws and regulations permitting Medicare managed care incentive plans.⁷
- b. Physician Self-Referral ("Stark") law. The Stark law, 42 U.S.C. § 1395nn, prohibits physician referrals to health care providers with which the physician (or an immediate family member) has a financial relationship. Compensation through gainsharing arguably creates that kind of financial relationship, and it remains a concern across both the Medicare fee-for-service and managed care populations. Thus, the Program must be structured to fit within an identified exception to the law, established by both statute and regulation. To fall within such an exception, the Program would include, among other elements, a requirement that physician payments are within the Fair Market Value (FMV) for comparable services in the region and that compensation is based on performance, not on the volume or value of Medicare or Medicaid referrals.
- c. Anti-Kickback Statute (AKS). Under the AKS, 42 U.S.C. §1320a-7b(b), providers cannot solicit or receive kickbacks directly or indirectly in exchange for Medicare or Medicaid referrals; criminal and civil penalties may be imposed for doing so. Gainsharing payments could be perceived as such kickbacks, potentially steering a physician's referrals to the hospital making the payment. Many of the Program's features are designed to safeguard against such concerns.

In addition, New York State has state laws that are similar though arguably less burdensome than their Federal counterparts: we have a state-level physician self-referral (or "Stark" law), anti-kickback statute, and False Claims Act. Because of the similarity of the State and federal laws regarding self-referrals, arrangements that comply with Federal exceptions are generally deemed to be compliant with State law. Conversely, arrangements that fall outside of Federal laws create – at least – a risk of liability under State law. 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.

⁷ To foster compliance with the CMP prohibition, the Program would exclude Medicare and Medicaid fee-for-service populations altogether, as discussed previously. Moreover, the Program would incorporate robust quality controls to ensure that patient care is constantly protected and to reduce the risk of any indirect CMP violations due to unintended "spill-over" from the commercial population to the fee-for-service beneficiaries.

V. The Need for an Upper Limit to Guard Against Fraud and Abuse.

As the above discussion makes clear, fraud and abuse laws play a critical role in the development of any gain-sharing program. This is particularly true with respect to the Program's upper limit on physician payments. As we discuss next, absent the upper limit, the program simply could not function.

The upper limit is based on the Federal Physician Incentive Payment or PIP Rule (42 CFR 417.479), which has been relied on to establish a similar 25% global cap in the Federal government's existing gainsharing programs:

- http://www.cms.hhs.gov/Medicare/Demonstration-Projects/DemoProjectsEvalRpts/Downloads/DRA5007_Solicitation.pdf
- http://www.cms.gov/Medicare/Demonstration-Projects/DemoProjectsEvalRpts/downloads//PHCD_646_Solicitation.pdf

Thus, the upper limit is not arbitrary, nor it is an insignificant portion of the gainsharing program. The upper limit was set, based on Federal guidance in the area, to create assurances that participating hospitals would not run afoul of the controlling Federal fraud and abuse statutes. It is one of the most significant legal checks built into the program, and it is one, among many, that requires sign-off by independent outside legal counsel for every hospital that wishes to participate in the GNYHA/AMS program. This is an issue that has been reexamined and reaffirmed each time a member elects to join the gainsharing program, and it illustrates the participants' profound commitment to compliance with Federal law. It would be difficult to overstate providers' concerns with fraud and abuse liability in this area, and as such, it would be irresponsible to disregard matters of precedent like the 25% upper limit established by the Federal government through the demonstration programs.

Even though the program does include an upper limit, it is important to note that it does not negate the unilateral nature of the program, as there is no agreement among participating hospitals on what their caps will be. Specifically, there is no cap *per se* on saved gains shared, though it is a program requirement that there be actual savings before any payments can be made to the physicians. Likewise, there is no agreement on the hospital-specific caps participating members impose; hospitals can determine what proportion of savings will be paid based on internal measures they have established within the bounds of applicable fraud and abuse guidance.

It is also important to note that, while individual hospitals have expressed interest in participating in a gainsharing program based on a methodology previously developed by AMS and approved for use in the limited Federal demonstration projects in this area, the hospitals themselves have not banded together to create a new, uniform arrangement. Rather, each has individually decided to contract with a consultant offering a service, just as if each was purchasing a new IT system that it could then adapt to its own needs.

Within the bounds of the gainsharing program, each hospital sets a *hospital-specific cap*, or the amount of money available for physician payments to its participating physicians. These hospital-specific caps can vary, and there is no agreement among the hospitals as to where they should be set. In fact, one hospital has already chosen to set this cap at 0% and will not offer any

payments to participating physicians. This hospital-specific cap is among the variations (such as actual differences in hospital costs) and customization (such as hospital-specific quality metrics) built into the program to reduce the likelihood of uniformity in incentive payments made to physicians.

II. Antitrust Analysis

GNYPHA believes that the Program brings to market an innovative, output expanding, and pro-competitive model for its member hospitals to lower physician costs while maintaining or improving quality of care. As such, this is one of the “many ways under the federal antitrust laws for providers to form joint ventures to control costs and improve quality without unduly inhibiting competition.” *See C. Varney, Antitrust and Healthcare*, at 12 (May 24, 2010).

The proposed Program does not inhibit competition in any way. The Program does not involve any agreement, coordination, or discussion concerning the prices that participating hospitals or physicians charge for their services. Thus, the Program does not implicate the concerns that arise in connection with collaborations involving joint contracting with health plans or other payers. *Cf. Id.* at 13 (noting that joint contracting may raise antitrust concerns, but may be justified if there is sufficient clinical integration); *citing* FTC Staff Advisory Op., *TriState Health Partners, Inc.* (April 13, 2009).

Nor does the Program involve any joint decision making or collaboration among physicians. Participating physicians, of course, must choose whether to participate in the Program, but there is no discussion, agreement, joint-price-setting or coordination at the physician or any other level. Rather, as with any compensation system, it is the hospital that chooses the amount, level, and terms of any incentives paid to physicians under the Program within the necessary methodology.

In that regard, it is important to note that each hospital sets the amounts of any incentives paid under the Program, subject only to certain limitations necessary to guard against fraud and abuse. Thus, this is one of the collaborations that does “not end competition among the participants and the collaboration,” since each of the participants “independently markets and set prices” for their services and each retains “[c]ontrol over [the] key competitive variables.” *See FTC and DOJ Antitrust Guidelines For Collaborations Among Competitors*, at § 3.34, p 18 (April 2000).

Moreover, as the FTC and DOJ have noted, “the use of significant financial incentives to achieve specific-cost containment goals” is pro-competitive and can justify a wide range of collaborative activities. *See Id.*; *see also FTC and DOJ Health Care Policy Statements*, at Statement 8.A.4. Here, the Program provides incentives for physicians to increase quality and efficiency, and does not provide any incentive to raise price. Incentive payments are only provided under the Program to recognize efficiency and reduced costs of treating patients if physicians maintain high levels of performance. Such incentives lower costs and enhance competition.

Similarly, the information exchanges contemplated by the Program are also procompetitive and consistent with the types of information exchanges the Division has historically approved. For example, the Division approved a system designed to allow “hospitals to determine how a given hospital’s charges for providing specified services compare to the average charges for providing the same service.” *Response to Pacific Business Group on Health’s Request for Business Review Letter* (April 26, 2010). In similar fashion, shared data for the GNYHA Program would not contain competitively sensitive information, and any distributions to hospitals and physicians would be aggregated and anonymized, making it unlikely to produce anticompetitive information-sharing effects. Hospitals will only see their own data, which will not be shared among other Program participants.

Each of the safeguards designed to prevent fraud and abuse and to otherwise comply with applicable rules and regulations are reasonably ancillary to the overall legitimate purposes of the Program, are the least restrictive means possible to achieve the Program’s purposes, and are procompetitive. These safeguards are consistent with the demonstration programs being conducted under the guidance of CMS. This should provide a strong indication that the safeguards are reasonably necessary, not unduly restrictive, and unlikely to diminish competition. *Cf. FTC and DOJ Proposed Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations*, at 5 (generally noting in the context of ACOs that “CMS’s proposed eligibility criteria are broadly consistent” with the Agencies Health Care Statements).

VI. Conclusion

GNYHA believes that this Program is necessary to help GNYHA members respond to the demands of health reform and tolerate the recent budget cuts on both the State and Federal levels. It is intended to build upon the programs hospitals are already developing and to promote creativity and enhanced quality of care, which will allow our hospitals to continue to serve their communities in a more efficient and streamlined manner.

GNYHA is confident that the Division will appreciate the efficiencies and procompetitive effects the Program will yield, particularly in light of the financial difficulties confronting the New York hospital market. As stated previously, participating hospitals will make independent decisions regarding their financial relationships with physicians and will share no competitively sensitive information or otherwise restrain competition. GNYHA will serve as a central resource for the Program, which is intended to benefit the greater New York health care community, but will not assist in any inappropriate sharing of information or anti-competitive behavior.

Please do not hesitate to contact us with any questions about the proposed Program. We would be pleased to supply you with more information or discuss any of the Program’s components at your convenience.

Sincerely,

/s/ *Colin R. Kass*

Colin Kass