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Andrew M. Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8013
Baltimore, MD 21244-1850

Subject: [CMS-1656-P] Medicare Program; Hospital Outpatient Prospective Payment and Ambulatory Surgery Center Payment Systems and Quality Reporting Programs; Payment to Certain Off-campus Outpatient Departments of a Provider; *Federal Register* / Vol. 81, No. 135 / July 14, 2016 / Proposed Rule.

Dear Mr. Slavitt:

On behalf of the more than 150 voluntary and public hospitals in four states that make up the acute care membership of the Greater New York Hospital Association (GNYHA), I appreciate this opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed rule for the calendar year (CY) 2017 outpatient prospective payment system (OPPS) and related programs.

By far, our most pressing concern in the proposed rule is the implementation of the site-neutral payment policies in Section 603 of the Bipartisan Budget Act of 2015 (BiBA). We urge CMS to delay implementation of the policies related to Section 603 to consider the complex and critical issues raised by the hospital industry and reevaluate its proposed policies, such as defining excepted services and sites. The delay would also give CMS time to implement systems changes to provide direct payment to hospitals for non-excepted services. Clearly, Section 603 was not meant to prevent hospitals from being paid for services furnished to Medicare beneficiaries.

Our comment letter also addresses the following topics:

- Meaningful use incentive payments
- Requirements for transplant centers and organ procurement organizations
- Removal of total knee replacement arthroscopy from the inpatient-only list and its effects on episode-based payment models
- Removal of the pain management questions from the hospital value-based purchasing program

If you have any questions or would like further information, please contact Elisabeth Wynn (212-259-0719/wynn@gnyha.org). For questions regarding our comments on the meaningful use provisions, please contact Zeynep Sumer-King (212-506-5315/zsumer@gnyha.org).

Sincerely,

Kenneth E. Raske

GNYHA Comments on the OPPS Proposed Rule

We organized our comments based on the order of topics in the proposed rule. We comment only on sections of the rule that pertain to our key concerns. Please note that our recommendations are highlighted in **bold blue** typeface.

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Implementation of Section 603 of the Bipartisan Budget Act of 2015 Relating to Payment for Off-Campus Departments of a Provider

The proposed rule outlines CMS's proposals implementing Section 603 of the Bipartisan Budget Act of 2015 (BiBA) related to payment policy for off-campus hospital outpatient departments (HOPDs). This issue is of great interest to our members because of the significant investments they have made in providing ambulatory care services to their communities in alignment with Federal and State policy goals.

Our members' investment in ambulatory care services extends far beyond "changing the shingle on an acquired physician office." Hospitals in New York State provide over 33 million clinic, ambulatory surgery, and emergency department visits annually—with roughly 75% of these visits being provided to Medicare, Medicaid, and uninsured patients.[1] Additionally, many of these sites are teaching clinics, providing the next generation of physicians with essential experience in outpatient care.

In the spirit of delivery system transformation, our members are also working on integrating primary care and behavioral health services, developing health home services, achieving patient-centered medical home status, and participating in Accountable Care Organizations (ACOs). For medically complex and fragile patients, including dual-eligible Medicare and Medicaid patients, these integrated models are the key to reducing health care spending without compromising access or quality. These good efforts should not be undermined by site-neutral payment policies.

The Medicare program already grossly underpays hospitals for outpatient services. A recent analysis from Medicare Payment Advisory Commission (MedPAC) showed that national Medicare margins declined in 2013 to -12.4%. In New York, the Medicare margin for our outpatient services, given our high proportion of not-for-profit, and public safety net and teaching hospitals, is an unsustainable -21%.[2] This is all before the payment reductions from Section 603 are implemented.

We recognize that Section 603 requires CMS to reduce payment for ambulatory care services provided at new, off-campus HOPDs. CMS's proposals go far beyond Congressional intent and will threaten the OPPS reimbursement for current HOPDs. In April 2016, more than half the members of Congress wrote to CMS unambiguously expressing their intention stating:

> *"As you plan for implementation of Section 603, we urge you to include flexibilities to enable hospitals to continue to serve patients in these settings. Specifically, we encourage you to include flexibility for those additional services provided at a dedicated emergency department, relocation or rebuilding for already existing HOPDs, change of ownership, and needed expansion of services and personnel to meet patient care needs of a community."*

CMS' proposed policies fail to heed this request by restricting the ability of hospitals to relocate existing services (seemingly even within the same building) or to modify services without jeopardizing OPPS

[1] GNYHA analysis of 2014 New York State Institutional Cost Reports.
[2] GNYHA analysis of 2014 Medicare cost reports.

reimbursement. Nor would CMS permit hospitals to acquire existing off-campus HOPDs in order to preserve access in communities when a hospital closes. These proposals are exceptionally narrow, and if finalized, will have significant repercussions for delivery system reform efforts. They are also administratively difficult to implement for both CMS and hospitals, as evidenced by the agency's proposal to provide no payment to hospitals for non-excepted services in 2017. Further, the agency has yet to detail how it would reimburse hospitals for these services in 2018 and beyond, or the operational billing requirements for hospitals to receive this reimbursement.

Therefore, GNYHA strongly urges CMS to delay implementation of the policies related to Section 603. A delay would provide time for CMS to reconsider the concerns of the hospital industry on issues such as relocation and expansion of services, while also allowing the agency to operationalize the policies and develop a mechanism to pay hospitals directly for non-excepted services. It would be rash for CMS to take any other approach—clearly Section 603 was not meant to change the OPPS reimbursement currently received by off-campus HOPDs or to prevent a hospital from receiving any reimbursement for services provided at newer sites.

Proposed Exemption of Services Provided at Dedicated Emergency Departments, On-Campus, and Remote Locations

CMS proposes several policies to implement the specific exceptions under Section 603 for services provided at dedicated emergency departments, on-campus, and at remote locations.

Services Furnished at Dedicated Emergency Departments

Section 603 of BiBA expressly exempts dedicated emergency departments that are not located on the campus or a remote campus of a hospital from the site neutral payment policy. CMS proposes to use the existing regulatory definition of dedicated emergency departments in §489.24(b) for this purpose. Specifically, a dedicated emergency department must meet at least one of the following requirements:

- It is licensed by the state in which it is located under applicable state law as an emergency room or emergency department;
- It is held out to the public (by name, posted signs, advertising, or other means) as a place that provides care for emergency medical conditions on an urgent basis without requiring a previously scheduled appointment; or,
- During the calendar year immediately preceding the calendar year in which a determination this section is being made, based on a representative sample of patient visits that occurred during that calendar year, it provides at least one-third of all of its outpatient visits for the treatment of emergency medical conditions on an urgent basis without requiring a previously scheduled appointments.

GNYHA supports both the definition of dedicated emergency departments and the proposal to exempt both emergency and non-emergency services provided at these locations from the site-neutral payment policy. Freestanding emergency departments are a common and growing part of the health care delivery system. In particular, as hospitals downsize and convert excess inpatient bed capacity

to alternative care models, the importance of freestanding emergency departments to the continued delivery of health care in inner city and rural communities will grow.

On-Campus Locations

CMS proposes to use the existing regulatory definition in §413.65(a)(2) to define on-campus locations that would be exempt from the site neutral payment policies. This definition generally defines the campus as, "buildings located within 250 yards of the main buildings of the hospital, and any other areas determined on an individual basis, by the CMS Regional Office, to be part of the provider's campus."

GNYHA appreciates CMS's acknowledgement of the role of the Regional Office in making these determinations given their understanding of local delivery system issues. **We request that CMS work with the Regional Offices to ensure that a standard of "reasonable flexibility" is employed in making such determinations given the geographic and other constraints that certain hospitals may face due to their location.** We also believe it would be helpful for hospitals to have an opportunity to meet with appropriate personnel from the Regional Office to discuss their building plans in advance of submitting provider-based attestations for new locations (and we have already submitted such a request to the New York Regional Office on behalf of our members).

Finally, CMS should consider creating an exceptions process for hospitals meeting certain criteria, such as being located in an area with land restrictions or barriers (natural or otherwise) in the area that immediately surround the main buildings of the hospital. Hospitals located in inner-city urban areas or surrounded by rivers or other geographic barriers face unique challenges in defining a campus for this purpose and it would be appropriate for CMS to consider these issues in making on-campus determinations. Criteria that CMS might consider include walkability or other accessibility measures to the location, presence of geographic or other barriers that render the 250-yard criteria impractical, attempts by the hospitals to build at a location closer to the main hospital buildings, and the type of services being provided at the location.

Within the Distance from Remote Locations

Section 603 also exempts services provided at remote locations of hospitals from the site neutral payment policies. Remote locations are defined by the Medicare program under §413.65(a)(2) as a "facility or organization that is either created by, or acquired by, a hospital that is a main provider for the purpose of furnishing inpatient hospital services under the name, ownership, and financial and administrative control of the main provider."

CMS also proposes to provide a 250-yard radius from such locations when making a determination of on-campus for this purpose. **GNYHA supports this proposal but encourages CMS to confer the same flexibilities to on-campus determinations as discussed above.**

Main Campus and Remote Locations Converted to an Ambulatory Care Facility

Given the specific protections in Section 603 for services provided at dedicated emergency departments and remote locations, we believe that it follows that Congress intended for the exemption to be maintained when an inpatient hospital (whether a main campus or remote location) downsizes its inpatient capacity and converts to an ambulatory care-only facility. The nomenclature for this delivery system

model is still evolving but is commonly referred to as a "medical village." Often, but not always, these facilities are structured such that emergency services are maintained, but importantly, so are primary and specialty care clinic services and ambulatory surgery services.

Conversions of inpatient hospital campuses to ambulatory care facilities are rapidly increasing as hospitals restructure their delivery systems to meet Federal and state health reform goals to provide more efficient and cost effective care, while enhancing access and improving quality. In a prior era, when inpatient hospital services closed, so did the entire medical complex and access to services for the affected communities ceased. Medicare beneficiaries and other patients were forced to find new sources of medical care, which was incredibly disruptive for patients with medically complex care needs. Now, hospitals are preserving access by converting these facilities to medical villages providing robust ambulatory care services.

We expect that the number of hospital conversions will continue to expand. Our members are actively working on initiatives to reduce unnecessary inpatient utilization, including efforts to right-size the inpatient capacity, while ensuring that patients have expanded access to ambulatory care services. It is a foundation of the efforts underway as our members implement projects under the New York State Delivery System Reform Incentive Payment (DSRIP) program under New York State's 1115 Medicaid waiver, and supported with dedicated capital funding from New York State.

For example, HealthAlliance of the Hudson Valley (HAHV), a two-hospital system in New York State, each with 150 inpatient beds, plans to close the inpatient beds at its Broadway Campus location and consolidate these services at its St. Mary's Avenue Campus. The inpatient bed capacity at the St. Mary's Avenue Campus will increase from 150 to 200 to ensure continued access to inpatient services for the community. Each campus currently has a separate Medicare provider number but will consolidate to a single provider with the closure of the inpatient services at the Broadway Campus. The Broadway Campus will provide robust ambulatory care services, including primary care and behavioral health services.

As of November 2, 2015, the Broadway Campus was licensed as an acute hospital, providing inpatient and outpatient services. In 2018 when the inpatient services are closed, it will become a provider-based off-campus HOPD of the St. Mary's Campus with one consolidated Medicare provider number. It appears CMS did not contemplate this scenario in the proposed rule. The closing hospital was not a remote campus (and will not be considered as such after the closure of the IP beds), it is not a freestanding ED, and it was technically not an off-campus HOPD as of the date of enactment of Section 603. Even if it provided emergency department services, the other ambulatory care services provided at the location (primary care, behavioral health, and ambulatory surgery) would be at-risk for reduced payment.

Therefore, CMS should except all services provided at off-campus HOPDs operating on the campus of a closed hospital (main or remote location) regardless of the site's status as of the date of Section 603's enactment. Without this exception, hospital conversions would not be financially viable, leading to a total hospital closure (of inpatient and outpatient services) and reduced access for beneficiaries, and putting medically complex patients at risk. It would also create a perverse incentive for hospitals to

maintain a few costly inpatient beds solely for the purpose maintaining OPPS reimbursement for the ambulatory care services.

Proposed Applicability of the Exception for Existing Off-Campus Locations

In addition to the specific exceptions for services provided at dedicated emergency departments, on-campus locations, and remote locations, Section 603 exempts sites that furnished services to Medicare beneficiaries as of November 2, 2015, from the applicable payment changes. CMS refers to these services as excepted services and proposes to define these locations/services in §419.48 as services provided "by an off-campus provider-based department that submitted a bill for a covered OPD service prior to November 2, 2015, are furnished at the same location that the provider was furnishing such services as of November 1, 2015, and are in the same clinical family of services as the services that the provider furnished prior to November 2, 2015."

GNYHA is very concerned that the proposed regulatory definition would threaten the intended excepted status of existing locations and urges CMS to rethink its approach. There is widespread evidence that Congressional intent was to protect existing sites but prevent the acquisition and conversion of new locations. CMS's policy proposals extend far beyond this intention.

Identification of Sites that Were Furnishing Services Prior to Enactment

In implementing this provision, one of the issues that CMS must address is how to identify off-campus locations that were furnishing services prior to enactment of Section 603. While the preamble of the OPPS proposed rule is ambiguous on this measure, the proposed regulatory text at §419.48 provides that the exception would be applied to "an off-campus provider-based department that submitted a bill for a covered OPD service prior to November 2, 2015." GNYHA is concerned that this could be interpreted in a narrow manner that would cause locations that were providing services prior to November 2, 2015, to be subject to payment reductions.

We are aware of several examples where hospitals were furnishing services to Medicare beneficiaries at off-campus outpatient locations on November 2, 2015, but had not yet submitted a bill for such services as of that date. There is a fine, but critical, distinction between furnishing and billing for services for this purpose. For example, in one case, a hospital opened an off-campus location providing chemotherapy infusion services in October 2015, but given that infusion therapies are routinely billed on a monthly basis and normal claim lags, did not submit a bill for the services provided in October 2015 until mid-November 2015. Another provider opened two off-campus locations in August 2015 and submitted an amendment to its 855-A Medicare enrollment application to reflect the new sites timely, but has not (as of September 1, 2016) received Regional Office approval of these locations. Therefore, while the provider began providing services prior to November 1, 2015, because of the extreme enrollment delay from Regional Office review of the application, it has not yet billed the Medicare program for services furnished to Medicare beneficiaries. Once approved, the provider would be permitted to bill for services for the past 12 months under the Medicare timely filing provisions. We expect this approval to happen very soon and that the provider would then be eligible to submit a bill for services provided as early as September 2015.

Clearly, both of these providers were furnishing services at the applicable off-campus locations before November 2015 for which they a bill either already has or will be submitted. In neither case should the Section 603 payment policies apply. **GNYHA recommends that the proposed regulatory language in §419.48 be modified to make clear that off-campus locations where services were being furnished prior to November 2, 2015, would be considered excepted as follows— "an off-campus provider-based department that submitted a bill for a covered OPD service furnished prior to November 2, 2015."**

We believe that this interpretation is supported by Section 603, which states "the term 'off-campus outpatient department of a provider' shall not include a department of a provider (as so defined) that was billing under this subsection with respect to covered OPD services furnished prior to the date of enactment of this paragraph." Here the distinction is clearly whether services were furnished before the date of enactment and the regulatory text should be modified accordingly.

We also strongly encourage CMS to explore whether it has the discretion to except sites that were mid-build as of November 2, 2015. The financial implications for these facilities are particularly damaging as the Section 603 unexpectedly changed the financial feasibility of such locations overnight. **If CMS determines that it does not have such authority, we urge Congress to enact legislation to except these locations.**

Relocation of Off-Campus Departments

GNYHA strongly opposes the proposed limitations on the ability of a provider to relocate an excepted off-campus department. CMS's limitation on relocation goes far beyond Congressional intent based on the plain language of Section 603 by narrowly defining excepted locations as those addresses listed on the provider's enrollment form as of November 1, 2015. Further, in cases with multiple units, such as a multi-office building, the agency would consider the unit number as part of the address so that a hospital would be precluded from expanding into other units in the building and remain excepted. These policies would effectively prevent any relocation of services without the hospital losing their current OPPS reimbursement.

There are numerous reasons why a provider would need to relocate an HOPD. In addition to those cited by CMS in the proposed rule related to natural disasters or other extraordinary reasons, relatively routine reasons such as the expiration of leases, a routine occurrence especially in urban areas where the high cost of real estate often prohibits purchase, efforts to improve crumbling capital structures and expand access, consolidate services to be more cost efficient or improve access for patients. Far from an attempt to skirt the Section 603 payment changes, these are routine occurrences and should not cause hospitals financial harm.

One academic medical center located in New York City leases space for nearly all of its dozens of primary care clinics. As these leases expire over the next several years, they may be forced to relocate these services to alternative spaces if they are unable to reach reasonable lease terms with the property owners. The mere expiration of a lease should not cause this hospital, or any other hospital, to lose its excepted status and threatening the financial feasibility of continued services.

Another member hospital is planning to consolidate HIV/AIDS services, currently provided at three different locations, into one location in the geographic area where their patients live to improve patient access and experience of care, while reducing costs. These are worthy goals that should not carry a financial impact—the Medicare program should be encouraging and supporting this type of activity, not providing a strong disincentive.

CMS's intention to apply the excepted status to the suite/unit number is excessively restrictive and completely impractical from an administrative perspective. When combined with the companion proposal to limit excepted services to those that were provided as of November 1, 2015, the proposal appears to limit or restrict routine occurrences such as relocating services within an HOPD. Certainly, this type of routine restructuring was not meant to be precluded and over time, will unravel the delivery of hospital ambulatory care services in the community.

If CMS is concerned about unrestricted growth of HOPD services, if facilities were permitted to relocate, it could adopt criteria, such as those used in the relocation of Critical Access Hospitals (CAH). The CAH relocation provisions include a multi-pronged 75% test—75% of the service area, 75% of the services, and 75% of the same staff—to put reasonable restrictions on changes. **We urge CMS to adopt a similar approach for relocations of excepted HOPDs—this would strike a reasonable balance between protecting against unfettered growth of services while still allowing hospitals to relocate and restructure their delivery systems.**

As noted by CMS, in some cases, hospitals may be required to move to fulfill Federal or state regulatory requirements or due to natural disasters. **As recommended above, we strongly believe that CMS should adopt a more reasonable relocation policy, but if the agency declines this approach, we would support an exceptions process for hospitals meeting certain requirements.** In addition to those situations identified by CMS, expiration of leases, the closing of inpatient capacity at a hospital and conversion to a medical village, or relocation of services within an HOPD should also be included. If it finalizes such a process, CMS should utilize a provider attestation process rather than a formal CMS approval process, which may cause unnecessary administrative delays. CMS would have the ability to recoup any overpayments if a provider was found to be out of compliance so we believe the program risk associated with this proposal is minimal.

Expansion of Services at Off-Campus Departments

CMS proposes to apply excepted status to only those "services" that were provided at an excepted location before November 2, 2015. In this context, CMS proposes 19 different families of services by ambulatory payment classification (APC).

GNYHA opposes this proposal because it instills an unnecessary level of complexity and provides a disincentive for hospitals to innovate care delivery. Hospitals routinely relocate services at HOPDs, adding and subtracting services based on community need. While hospitals would likely try to limit this activity in the future if there were associated reimbursement implications, some level of service changes is unavoidable. This means that over time, many HOPDs would be providing a mix of excepted and non-excepted services at off-campus HOPDs. Beyond the administrative and compliance concerns of ensuring that services are appropriately billed, it is unclear how CMS would treat these locations for other policies

such counting time for residency training/rotations, allocating hospital costs on the cost report, conditions of participation for co-located sites, and other provider-based requirements. We are concerned that it may also have repercussions for 340B eligibility.

From a technical perspective, we noted that several current APCs are not captured in the family of services proposal. Most of these are new technologies, drugs, and devices/procedures that were not paid for under OPPS in 2015. From the proposed rule, it's unclear whether CMS's intention is to exclude these APCs from the policy? How would CMS handle the migration of services from the inpatient setting to the outpatient setting as the inpatient only list is updated annually? Would these "new" outpatient services be automatically considered non-excepted services?

Interaction of Relocation and Service Expansion Proposals

When the relocation and service expansion proposals are combined, hospitals would have no flexibility to continue to innovate their delivery models without significant reimbursement implications. Under CMS's proposal, a hospital could seemingly move services within existing HOPDs (limited to suites/offices that were providing hospital-based services on November 1, 2015), but only if the APC family of services being provided was the same. However, if a hospital were providing imaging in Suite A and cardiology services in Suite B, they seemingly could not "swap" locations within the same building because the APC family of services is different.

A hospital in our membership is in the midst of a major renovation of a multi-story off-campus HOPD that opened in the mid-1990s. As part of its plans, it intends to relocate existing services within the HOPD to enhance patient access and improve the experience of care. For example, it plans to move cardiology services to the current gynecology services space; move gynecology to the space where primary care services are located; etc. These modifications are meant to improve patient-flow and efficiency by locating services and associated ancillary services closer together. However, it appears that simply restructuring existing services within an excepted off-campus HOPD would threaten their excepted status.

We don't believe that this could possibly be CMS's intention—and most certainly was not Congress's—and urge the agency to reconsider its relocation and service limit proposals. When combined, these policies unnecessarily encumber hospitals from making any changes to their community-based ambulatory services without significant financial consequences.

Changes of Ownership/Mergers and Acquisitions and Excepted Status

GNYHA opposes CMS's proposal to limit transfers of excepted status in changes of ownership and mergers/acquisitions to scenarios where the ownership of the main provider is also transferred and the acquiring hospital accepts the Medicare provider agreement. Again, CMS has failed to consider the implications that such a policy would have on continued access to care. Most frequently, the reason that a hospital would want to acquire an HOPD from another hospital (without transfer of ownership of the main provider) is in cases of a hospital closure. In many, but not certainly not all, there is a bankruptcy proceeding that is associated with the closure. Nearby hospitals located in the community often acquire these off-campus HOPDs to ensure that access to ambulatory care services is maintained, even though the main hospital was financially unsustainable and the inpatient services are closing. CMS's

proposal threatens the financial viability of such transactions and therefore, continuity of care for communities.

CMS's policy also appears to rescind the excepted status of HOPDs in certain mergers where the main provider is acquired. **We believe that in all of the following scenarios, the excepted status of the acquired off-campus HOPDs should continue under the new owner. GNYHA urges CMS to clarify its change of ownership and merger/acquisition policies accordingly in the final rule.**

- Scenario 1. Change of ownership: The parent corporation of Hospital A (XYZ Hospital Corporation) acquires Hospital B. Hospital A and Hospital B continue to bill under their separate (existing) provider numbers after the change in ownership. Accordingly, the parent corporation also accepts the Medicare provider agreement of Hospital B.
- Scenario 2. Merger/Acquisition: The parent corporation of a hospital system, XYZ Hospital Corporation completes a full asset merger and consolidates the provider numbers of Hospital A and Hospital B under one provider number. The provider number of Hospital A is the surviving entity and the provider number for Hospital B is voluntarily terminated. Hospital A accepts assignment of the Medicare liabilities associated with Hospital B's provider number.
- Scenario 3. Merger/Acquisition: Hospital A and Hospital B, each with separate provider numbers, consolidate operations under a new provider number and the provider numbers of the existing entities are retired. The newly created provider accepts assignment of the Medicare liabilities from the retired provider numbers.

Data Collection Necessary to Identify Excepted Locations and Sites

CMS does not currently collect or maintain a database with the information necessary to identify excepted sites and services. In thinking through implementation steps, we agree that a new data collection process would be preferable to adding a new field to the current 855-A Provider Enrollment Application database. However, we take the opportunity to point out that in order to implement its proposed policies, CMS would need to collect information on every single off-campus location (down to the suite number according to its proposal) and the services that were being provided in those locations as of November 1, 2015. This is completely unworkable and would be a massive administrative undertaking for hospitals to compile and report on a regular basis as any changes to sites or services are made. This is reason enough for CMS to rethink its approach to relocation and service expansion.

Payment for Services Furnished in Non-Excepted Locations

Applicable Payment Policy for 2017

For 2017, due to claims processing systems limitations, CMS does not have the ability to pay hospitals for non-excepted services. This is somewhat perplexing because CMS already pays hospitals under the Medicare physician fee schedule (MPFS) for some services such as screening mammography, physical therapy services, and some preventive services. Its proposed alternative approach is to permit physicians to bill for both the technical and professional components for non-excepted services under the MPFS and remit payment to hospitals through contractual arrangements. **This proposal is simply impractical, unworkable, and must be rescinded—it will result in hospitals receiving no payment for non-excepted services provided in 2017, which will cause hospitals significant financial harm.**

In addition to raising serious legal and regulatory concerns for hospitals and physicians, there are also many technical and logistical issues that are not addressed by CMS. For example, we have identified many services for which there is not a technical fee and therefore, no payment would be made for the hospital services. **CMS must delay implementation of Section 603 and its related policies until it can develop a mechanism to pay hospitals directly for non-excepted services. Nothing in Section 603 was meant to preclude hospitals from being paid for services furnished to Medicare beneficiaries. A delay would also give the agency time to reconsider its proposals on identifying excepted services/sites.** This certainly would not be the first time that CMS delayed implementation of a major policy change because there was insufficient time to operationalize the changes. Examples include implementation of the OPPS, clinical laboratory fee schedule, and ambulance fee schedule.

Legal and Regulatory Exposure

The proposal places hospitals and physicians in an untenable position where they may incur legal and regulatory exposure through no fault of their own. As CMS acknowledges, this approach would require a revised financial relationship between the affected hospitals and their physicians, which implicates the physician self-referral ("Stark") laws as well as numerous laws and regulations including the Anti-Kickback statute, tax exempt bond financed space use constraints, fee-splitting and corporate practice rules. In addition, since the space will, in most cases, still be operated as a hospital service (for 340B purposes among others), the arrangement must still comply with the provider-based rules applicable to such settings. The failure to comply with Stark could lead to overpayments, civil monetary penalties and False Claims Act liability. The failure to comply with the provider-based rule could also result in overpayments, as well as loss of the hospital's right to participate in the 340B program, if applicable. The failure to comply with tax-exempt bond financing requirements would be loss of the exemption for income on the bonds.

The stakes are therefore quite high. However, it is unlikely that hospitals and physicians will be able to comply with both the Stark laws and the provider-based rule under the circumstances. Hospitals maintain a variety of arrangements with physicians. While full-time employment arrangements have significantly increased in recent years, most hospitals still have a blend of employed and voluntary/contracted medical staff; compliance is significantly more complicated in the latter case.

With respect to the proposed interim billing arrangement, there are few good options for Stark compliance, for example, and those that do exist may conflict with the provider-based rule. To comply with the Stark exceptions for space and equipment leases, the physician would need to be in control of the space or equipment, which could violate the provider-based rule. The newly implemented exception for timeshare arrangements could be a better option; however, it will not apply in all circumstances. For example, the timeshare exception requires that the physician use the hospital's premises, equipment, personnel, and supplies predominantly for the provision of evaluation and management services, and it excludes the use of advanced imaging equipment. Additionally, the compensation paid by the physician to the hospital under both the leasing and timeshare exceptions must be consistent with fair market value.

For the timeshare exception, the compensation may not be based on a percentage of revenues billed or collected for the service, or any per-unit service fees that are not time-based. The facility portion of the reimbursement under the MPFS may well not be sufficiently high to satisfy the fair market value analysis;

the facility portion of the MPFS is not designed to address the extensive costs incurred by the hospital in operating an HOPD. Theoretically, physicians could pay the full amount of the facility fee that the hospital would otherwise have received, but such an arrangement could violate the prohibition on percentage based or per-unit of services compensation methodologies and may not be fair market value or commercially reasonable.

Even if CMS were to waive compliance with the provider-based rules in these off-site facilities, from a practical standpoint, regardless of which Stark exception or other compliant structure for the other laws at issue is pursued, timing is a significant obstacle. As noted above, hospital-physician arrangements must be documented in order to demonstrate compliance with Stark. A reopening of existing arrangements, with the attendant renegotiation, legal analysis and expense would need to be performed for every physician participating in the billing arrangement contemplated by the proposed rule. Given that the proposed rule will not be finalized until approximately November 1, 2016, with an effective date of January 2017, there is not sufficient time to take all of the steps necessary to create compliant arrangements. It is wasteful and unnecessary to devote months to changing arrangements that will be in place only a year. Moreover, under the Stark contract restrictions on changes to arrangements, it may not be legally possible to make these changes in time.

CMS's proposed billing approach places hospitals and physicians in an untenable position where they may incur exposure under the Stark law or provider-based rule through no fault of their own and must be delayed. While CMS waivers of the applicable portions of the provider-based rule and Stark laws could offer some protections, we don't believe that such waivers would go far enough to limit legal and regulatory exposure. Also, there simply isn't sufficient time between publication of the final rule in November 2016 and implementation in January 2017 for hospitals to appropriately work through these issues with their physicians.

340B Eligibility of Non-Excepted Sites

Although the proposed rule stated that non-exempt off-campus sites would still be considered provider-based, it did not specifically address any potential impact on eligibility for the 340B program. The 340B program requires drug manufacturers to offer discounts on outpatient drugs to certain hospitals that provide services to vulnerable patient populations. One of the eligibility requirements for receiving the 340B discount is that a hospital site must be considered reimbursable on the Medicare cost report; in general, services are considered reimbursable on the Medicare cost report when they are paid on an institutional claim.

We are concerned about the potential implications of CMS's proposal not to reimburse hospitals for non-excepted services in 2017, as well as any future policy proposals in this regard, on 340B eligibility. **GNYHA requests that CMS clarify that non-excepted sites and services would remain reimbursable on the Medicare cost report, and work with the Health Resources and Services Administration to ensure that they remain eligible for 340B pricing.**

Technical Issues with the 2017 Billing Policy Proposal

In addition to the significant legal concerns, there are numerous technical issues with CMS's proposal. A review of the MPFS identified many services for which there is either site of service differential or no

MPFS rate for the service period. Therefore, if a hospital provides these services in 2017, there is no opportunity for them to receive any reimbursement even if they were able to work through the contractual issues with the physician providing the service. CMS's suggestion that a non-excepted HOPD could simply change its enrollment to an alternative provider type such as a physician office or ambulatory surgery center (ASC) in order to receive payment in 2017 is severely flawed. Such a change in enrollment would take several months and an even longer delay could be expected in states like New York with strict Certificate of Need (CON) laws (assuming that the HOPD could even meet the regulatory ASC regulatory requirements).

This also fails to address fundamental problems with CMS's proposal—that many services furnished by HOPDs don't have a site of service differential under the MPFS. For example, a New York hospital opened an HOPD that is at-risk of being considered off-campus in 2016 after a multi-year building process. The HOPD is furnishing a mix of services, including ambulatory surgery, infusion, and other services. In reviewing this proposal, they found that 90% of the services provided at this location do not have a site of service differential so they have no opportunity to receive payment. Enrolling as an ASC is also impractical for this provider because they furnish many surgical procedures that do not meet the ASC regulatory requirements that the procedure be completed in less than 24 hours. Therefore, this provider has few options in order to receive any Medicare payment.

We are also concerned about the impact on partial hospitalization services. Medicare only pays for this service when furnished by a hospital or community mental health clinic. There is no MPFS rate. How would CMS preserve access to these needed services?

There are many other unanswered questions about the proposal. How would a hospital capture this revenue for reporting on the Medicare cost report since the revenue would not flow through the Provider Statistical and Reimbursement (PS&R) report? How would costs and revenues be apportioned across excepted and non-excepted services furnished in the same location? With respect to the payments made to the physicians, how would this revenue be reported for tax purposes—for both physicians and for-profit hospitals? How would this revenue/spending impact metrics such as Medicare spending per beneficiary, the value modifier, other efficiency measures?

Impact on Behavioral Health Services

GNYHA is also very concerned about the deleterious effect these proposals will have on access to behavioral health services. As we discussed earlier, there is no reimbursement outside of the OPPS for partial hospitalization programs. In addition, we are concerned about the implications for services such as counseling/psychiatric visits that are often provided by residents in teaching clinics. Because of the sensitive nature of the sessions, the supervising physician is rarely in the room providing personal supervision of the session. Therefore, there is currently no Part B claim submitted for these services, only the OPPS bill for the facility costs. Under the proposed rule, hospitals furnishing these services would either have to completely overhaul their staffing model so that the attending was present or forego any reimbursement for these services. This is just another of the myriad reasons for CMS to rethink its proposals for 2017.

Applicable Payment Policy for 2018 and Other Considerations

CMS must go back to the drawing board and rethink the payment policies for non-excepted services. CMS should consider convening a Technical Expert Panel or other like body to make recommendations on these issues in advance of rulemaking for 2018. In the interim, GNYHA puts forward the following comments:

- Hospitals must be able to directly bill and be paid for services provided to Medicare beneficiaries. In situations where there is currently no site-of-service payment differential, CMS should create an applicable payment rate. A new provider/supplier type should not be established for this purpose—these locations are provider-based HOPDs.
- The hospital billing should continue on the institutional claim with a modifier to indicate that the services provided were non-excepted. Billing on a professional claim for these services would be administratively burdensome and potentially has implications for the three-day DRG payment window and other provider-based requirements.
- The revenue for the services should be captured on the PS&R and reported on the Medicare cost report.
- There are many technical rate setting issues that need to be thought through, including:
    - Impact on APC weight development and related cost finding (development of ratio of cost-to-charges), especially for services that have different packaging policies across payment systems;
    - Development of appropriate payment policy when a technical payment rate does not currently exist;
    - Appropriate handling of different coding conventions, billing modifiers/requirements, place of service codes, etc. across claim types; and,
    - Impact on beneficiary copayments and coinsurance.

Proposed Changes to the Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs

CMS proposes a number of modifications to the Medicare and Medicaid EHR Incentive Programs in the proposed rule, including:

- a 90-day reporting period for all providers in CY 2016;
- eliminating objectives and measures from the program;
- reducing the thresholds of a subset of the remaining objectives and measures in Modified Stage 2 and for Stage 3 in 2017 and 2018;
- a new attestation deadline for providers demonstrating meaningful use for the first time in 2017;
- a one-time hardship exception for EPs demonstrating meaningful use for the first time in 2017 and that plan to transition to MIPS; and
- a new policy for measure calculations for actions outside of the EHR reporting period.

The proposed changes to the meaningful use objectives and measures would apply to Medicare EHR Incentive Program participants only. Providers attesting to meaningful use under a state Medicaid EHR Incentive Program would continue to attest on the measures and objectives finalized in the 2015 EHR Incentive Programs Final Rule.

GNYHA greatly appreciates the increased flexibility that CMS has proposed for eligible hospitals (EHs) and eligible professionals (EPs) in 2017 and 2018. The proposed flexibility would provide much-needed relief to providers, would support continued adoption EHRs, and help facilitate the transition for EPs moving to MIPS. However, GNYHA does not think the proposed modifications address all significant barriers to EHR adoption and provide enough flexibility. Meaningful use requirements remain overly prescriptive and over the years, have forced providers to develop processes that do not add value to patient care to meet objectives and measure thresholds. Furthermore, in order to meet certain objectives, providers have had to adopt technology that is not fully developed or tested and therefore that did not meaningfully facilitate any portion of their patient care workflow. GNYHA has expressed many of these concerns to CMS in the past and has included them in detail below, as they relate to the proposed changes to the EHR Incentive Programs.

EHR Reporting Period

The proposed rule modifies the EHR reporting period, allowing providers to select any consecutive 90-day period in CY 2016. This addresses a concern we previously expressed that EHR technology and interoperability have not advanced sufficiently to allow providers to meet certain objectives for a full calendar year. EHR vendors and providers have also not had sufficient time to incorporate updated certified electronic health record technology (CEHRT) specifications, including application program interface (API) requirements, introduced as part of the 2015 Edition CEHRT. **GNYHA supports CMS's proposal to allow all providers to attest to any consecutive 90-day period in CY 2016 and appreciates its acknowledgement of provider challenges.** However, we remain concerned that this proposal was introduced late, is overdue in addressing provider needs, and may not be finalized soon enough for providers to fully take advantage of the flexibilities offered. **We urge CMS to finalize this proposal as soon as possible without any narrowing of the flexibilities offered.**

GNYHA also supports moving to a 90-day reporting period for all subsequent years of the EHR Incentive Program. CMS has acknowledged provider difficulties and modified the reporting period multiple times. In fact, a 90-day reporting period is a strong indicator of provider adoption and meaningful use of EHRs. As long as EPs and EHs can attest to having installed a CEHRT for a full year, the accounting and attestation to objectives and measures should be limited to an abbreviated 90-day period. This will allow providers to focus on patient care and on innovative uses of technology to deliver better care, which will drive for market advancements in technology. We urge CMS to consider this proposal.

Removal of Objectives and Measures from the Meaningful Use Program

CMS proposes to remove two objectives—Clinical Decision Support and Computerized Provider Order Entry—and their associated measures from the EHR Incentive Program beginning in 2017 because it states they are topped out. **GNYHA supports CMS's topped out criteria and assessment, and the removal of these objectives from the program. GNYHA also appreciates that these objectives will remain as part of 2015 Edition CEHRT.** Providers have almost universally adopted these two EHR functions and eliminating the need to track and report on their use regularly allows providers to focus on

other important activities. However, by requiring these functions as part of EHR certification, CMS stresses the importance for EHR vendors to continue to maintain the capabilities and will relieve individual providers of the burden of negotiating their upkeep in the CEHRT.

Modifications to Objectives and Measures

In an effort to reduce provider burden, CMS proposes a number of modifications to existing objective and measure thresholds. CMS also proposes to streamline the naming conventions for certain objectives and measures. **GNYHA appreciates this streamlining. GNYHA also supports the general direction of CMS's modifications to measure thresholds, in that they reduce the overall burden for providers, but we have several concerns, as noted for each objective/measure below.** We support the proposed modifications to any measure that was modified, but that we have not addressed below.

Patient Electronic Access

GNYHA supports the proposed change to the View, Download and Transmit measure threshold from 5 percent of patients to at least one patient during the reporting period for modified stage 2 in 2017 and stage 3 in 2017 and 2018.

However, GNYHA opposes the stage 3 requirement to use API functionality for patient engagement for educational resources or for health information exchange. While APIs are available, they have not matured sufficiently nor have they been adopted and offered widely by EHR vendors. We are also opposed to an unrealistic 36-hour timeframe to make this information available. Due to the time it takes to coordinate care and verify information, this timeframe requirement would pose operational challenges to hospitals.

Coordination of Care through Patient Engagement

GNYHA supports the proposed change to the Measure 1 threshold from 10% of all unique patients to at least one patient. However, GNYHA opposes the stage 3 requirement to use API functionality for patient engagement with an EH's CEHRT. While APIs are available, they have not matured sufficiently and have not been adopted and offered widely by EHR vendors. GNYHA recommends CMS conduct a study to evaluate patient and provider experience to inform future requirements related to patient engagement.

GNYHA is opposed to the inclusion of Measure 2 as a requirement for EHs. Secure messaging does not typically align with EH providers' communication workflow with discharged patients. Instead, patients discharged from a hospital are more likely to communicate with primary care providers in the community. Therefore, the secure messaging requirement should be applicable only to EPs. If finalized as proposed, GNYHA recommends that CMS consider setting the EH threshold to at least one patient.

Lastly, GNYHA has concerns with Measure 3 and believes it is premature to set a threshold for incorporating patient-generated data from a non-clinical setting into the EHR. We believe this is a worthy goal, especially in the primary care setting. If CMS decides to maintain this measure as part of stage 3, we recommend eliminating the requirement for EHs or limiting the threshold to at least one patient to test functionality and the demand for such information.

Health Information Exchange

GNYHA appreciates the modified threshold in stage 3 for Measure 1 requiring EHs use their CEHRT to create and electronically transmit a summary of care for more than 10% of transitions.

We recommend also lowering the threshold for Measure 2, incorporating a summary of care document received from a source other than the provider's EHR from 10 percent to at least one patient that is transferred or referred. Providers have had significant technical problems with receiving an electronic summary of care document. We continue to support New York State's health information exchange efforts and ask that CMS also provide constructive support through testing of standards and by increasing other providers' capabilities to participate in information exchange.

While we appreciate the lower threshold for Measure 3, clinical information reconciliation, we do not agree that the proposed 50% threshold is reasonably achievable. As a new measure to the program in stage 3, the industry has no experience in implementing technology capable of clinical information reconciliation. We recommend significantly lower measure threshold be considered.

Public Health and Clinical Health Registry

GNYHA appreciates CMS reducing the number of required public health and clinical registry measures for EHs in stage 3 from four to three. However, EPs and EHs still struggle to identify the certified clinical registries to which they must submit measures. CMS could support these efforts by maintaining a list of clinical and public health registries that can support the active engagement requirement.

All-or-nothing approach

GNYHA encourages CMS to abandon its all-or-nothing approach to the meaningful use program. Under the current rules, providers' failure to meet any one of the Medicare EHR Incentive Program requirements, even by a small amount, has meant they would incur significant payment penalties. Hospitals, in particular, have invested millions of dollars and countless personnel to meeting the program requirements successfully and to making a good faith effort to maximize use of their EHRs. Given these investments, it seems unfair to have so much at stake for missing any single measure. Hospitals certainly recognize the value of technology in care delivery and that the EHR Incentive Programs have enabled widespread adoption of EHRs across hospitals and EPs. However, the programs have now matured and stakeholders and experts across health care agree that while the meaningful use program helped achieve widespread adoption of basic EHRs, prescriptive criteria and standards would only limit future growth and innovation. Market needs and priorities should drive the innovation, not reporting requirements. **CMS should allow providers greater flexibility in choosing which requirements to implement and develop a method for giving credit to those who make a good faith effort to adopt CEHRTs.**

Hardship Exceptions

To smooth the transition to MIPS, CMS proposes an added hardship exception to the Medicare EHR Incentive Program for EPs that have not successfully demonstrated meaningful use in prior years and that plan to transition to MIPS in CY 2017. **GNYHA appreciates the recognition of the distraction these EPs would face with having to meet both program requirements and supports the added hardship exception. We additionally propose that CMS expand the hardship exception criteria to include EPs and EHs that are transitioning to a new CEHRT.** Providers, and large health systems, in particular, face added challenges when implementing a new CEHRT while continuing to use an existing

CEHRT. In some ways, transitions from one EHR to another are more complex and take more time than an implementation where no EHR existed before. We urge CMS to add hardship exception criteria in recognition of these challenges.

Application of Changes to the Medicaid EHR Incentive Program

While CMS makes a number of changes to the EH meaningful use criteria, the proposed rule states that these changes would not apply to State Medicaid EHR Incentive Programs. Providers attesting under a state Medicaid Incentive Program would be subject to the objectives and measures finalized under the 2015 EHR Incentive Programs rule. If the proposed changes applied to Medicaid as well, CMS is concerned that states would have to implement major process changes within a short period of time which would include the burden of updating technology and reporting systems at a cost. **GNYHA has concerns about this misalignment in programs and urges CMS to apply the changes across both the Medicare and Medicaid programs to avoid added complexity.** To address states' lack of readiness, CMS could assess its ability to intake Medicaid-only attestations and communicate them to the States, as it currently does for Medicare and Medicaid EHs participating in both programs. This would leverage existing reporting and communication capabilities to ensure alignment across Medicare and Medicaid.

Requirements for Transplant Centers and Organ Procurement Organizations (OPOs)

Over the past decade, CMS has significantly changed the processes by which it oversees both organ transplantation and the performance of OPOs, in a way that has fostered continuous quality improvement in both the procurement and transplantation of donated organs. The proposed changes in the proposed rule further advance those efforts by modernizing the quantitative criteria for both performance standards for transplant centers and the conditions of participation for OPOs. GNYHA supports both the substance of those changes and the continuing effort to keep these statistical criteria consistent with up-to-date data and evolving professional consensus.

Removal of Total Knee Arthroplasty (TKA) from the Inpatient-Only (IPO) List and Impact on Episode-Based Payment Models

The decision to remove a procedure from the IPO list should be based on the clinical appropriateness of performing the procedure on an outpatient basis. From a clinical perspective, GNYHA does not have major concerns about removing the TKA procedure from the IPO list, although it would likely only be appropriate for a small subset of Medicare beneficiaries. If CMS ultimately decides to remove the TKA procedure from the IPO list, **CMS must appropriately risk-adjust the targets in the Comprehensive Care for Joint Replacement (CJR) and the Bundled Payment for Care Improvements (BPCI) models.** Should CMS decide to move forward, it should provide an opportunity for stakeholders to concurrently comment on the removal of TKA, and a risk-adjustment method to account for the removal in the agency's bundled payment initiatives. Accounting for the higher risk profiles of patients continuing

to receive TKA procedures on an inpatient basis is critical to ensuring accurate benchmarks and the integrity of these programs.

Removal of Pain Management Dimension from the Hospital Value-Based Purchasing (VBP) Program

GNYHA supports CMS's proposed removal of the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Pain Management dimension from the Hospital VBP Program beginning with the FY 2018 program year. GNYHA shares other stakeholders' concerns that linking the results of the pain management survey questions to payment under the VBP program puts pressure on hospital staff to prescribe opioids to achieve higher scores. This potential linkage is especially problematic in light of the prescription opioid overdose epidemic. Further, the results of the HCAHPS pain management questions in their current form may not accurately reflect the quality of care received at the hospital, as they do not factor in all elements of clinical decision-making and individual circumstances. Pain management is a critical component of patient care and GNYHA appreciates CMS's efforts to refine the survey questions to address these concerns. The modified questions should focus on additional aspects of pain management, including communicating expectations and shared decision-making with patients.

GNYHA also believes that publicly reporting the results of these questions on Hospital Compare through the Hospital Inpatient Quality Reporting (IQR) program could distort the perception of the quality of care provided at certain hospitals. **Therefore, GNYHA recommends that CMS remove the Pain Management dimension from the publicly available database under the IQR program while the questions are modified.**