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Re: OMIG Audit of Ancillary Services "Associated with" an "All-Inclusive General Clinic Visit."

Dear Robert:

I am submitting this letter to you in my capacity as Chair of the Payment and Reimbursement Committee of the Health Law Section of the New York State Bar Association. The purpose of this letter is to follow up on our conversation last week in which I raised significant concerns regarding the legal basis for the OMIG audit described below.

In September 2008, OMIG sent a letter ("OMIG Letter") to hospital clinics throughout the state seeking repayment of alleged overpayments identified as a result of a review of ancillary services "associated with a general clinic visit." In each of these letters, OMIG asserted that a general clinic visit is reimbursed on the basis of an "all-inclusive" clinic rate.

We understand that most hospitals have been given an extension of time to respond to the OMIG Letter until November 11, 2008, and in some cases until November 25, 2008 . For the reasons set forth in this letter, we respectfully suggest that OMIG either retract the OMIG Letter or put this audit on hold and grant providers a further extension of time while you examine the significant legal issues raised by this letter.

I. The OMIG Audit

The OMIG Letter attached 3 exhibits detailing the disallowed claims, which the letters categorize as follows:

> "Exhibit #1 Laboratory Services Billed Fee for Service that are included in the Threshold Clinic Rate"

"Exhibit #2 Ordered Ambulatory Services (Other than Labs) Billed Fee for Service that are included in the Threshold Clinic Rate - Facility Billed"

"Exhibit #3 Ordered Ambulatory Services (Other than Labs) Billed Fee for Service that are included in the Threshold Clinic Rate - Physician Billed."

Discussions with hospitals who have received these OMIG letters reveal that OMIG has included the following types of claims in these exhibits as alleged overpayments:

Exhibit #1: includes laboratory tests that a hospital performed itself, sent to a reference lab, or which an outside lab that is not a reference lab performed for a patient who happens to be registered as a clinic patient and who, sometime in the prior 30 days, received a service at a hospital clinic;

Exhibit #2: includes diagnostic services (such as PET scans) performed and billed by a facility (either the hospital or another facility) for a patient who, sometime in the prior 30 days, received a service as a registered hospital clinic patient: and

Exhibit #3: includes diagnostic services (other than lab tests) performed and billed by a physician office for a patient who, sometime in the prior 30 days, received a service at a hospital emergency department or clinic.

OMIG appears to have engaged in data mining and computer matching to capture in these three exhibits (a) any claim submitted to Medicaid by a hospital for a patient who was registered at a hospital outpatient clinic and (b) any claim submitted to Medicaid for any ancillary service provided to the same patient within the next thirty (30) days. OMIG appears to have treated as an overpayment to the hospital clinic any claim generated by this computer match, regardless of whether the claim is legally required to be packaged into the clinic rate. For example, it has included in these exhibits tests performed and billed by entities other than the hospital even where the hospital (i) has no obligation to contract with an outside facility or physician office to perform testing services on behalf of clinic patients, (ii) has no such contract and, therefore, (iii) has no costs associated with such tests in its clinic rate. This letter will describe existing New York law governing the reimbursement of hospitals for general clinic visits as well as for ordered ambulatory services, and explain why there is no legal basis for OMIG to disallow many of the claims listed in these three exhibits.

II. Summary of Legal Arguments

There no legal basis for OMIG to claim that "All ancillary services rendered and/or ordered as a result of a threshold clinic visit are included in the cost of the clinic visit and should not be billed fee for service." OMIG appears to be misapplying to general hospital clinics regulations that are, instead, applicable only to certain specialty hospital clinics, such as those serving PCAP patients or those designated as Preferred Primary Care Providers. Alternatively, OMIG appears to be applying - retroactively - the proposed new regulations in subpart 86-8 that have not yet been adopted or the Medicare outpatient hospital reimbursement rules proposed on August 5, 1988 that were never adopted. Either way, there is no legal basis under current New York law for: (1) holding general hospital outpatient clinics to be responsible for arranging for all ancillary services required by registered clinic patients, particularly ancillary services provided by outside entities, or (2) asserting that the capped clinic rate paid to general hospital clinics for operating costs ($67.50) includes all ancillary services provided by the hospital during a thirty day period to a patient who happens to be a registered clinic patient.

A. Base Year Costs Do Not Include the Costs of Outside Providers.

As we explain below, the rate for general hospital outpatient clinic services is cost-based, and the base year costs are not required to, and generally do not, include the costs of ancillary services rendered by outside providers. This is because such clinics are not currently required to "arrange for" ancillary services to be provided by outside providers. Instead, in the event that a hospital cannot provide the test itself, general hospital clinics are required to "refer" the patient to an outside provider. *See, e.g.,* 10 N.Y.C.R.R. § 405.20(c)(2). So long as the patient is not enrolled in a Medicaid managed care plan, the Medicaid patient retains freedom of choice to choose which outside provider will perform the test.

For the foregoing reasons, OMIG cannot claim that general hospital clinics should have paid for tests provided by outside providers and cannot impute to the clinic the cost to Medicaid of the test billed directly to Medicaid by the outside provider.

B. "Visits" vs Ordered Ambulatory Tests

If a hospital performs an ancillary test that has been ordered by a "physician's office," then the test is an ordered ambulatory test, and the hospital may bill Medicaid for the test under the applicable fee schedule. 10 N.Y.C.R.R. § 441.339. A general hospital clinic is not obligated to provide or arrange for all ambulatory care and testing required by a registered clinic patient. Clinics are licensed to provide discrete services, and some clinics are not licensed to provide a comprehensive range of services.

Moreover, a registered clinic patient is not required to obtain all ambulatory care from one clinic. Instead, clinic patients who have not enrolled in a Medicaid managed care program retain freedom of choice to go to any provider for diagnosis or treatment of a condition.

For the foregoing reasons, OMIG cannot treat, as part of one clinic visit, all ancillary services performed by the hospital within thirty (30) days of the date of a general clinic visit.

C. Cost/Visit Methodology.

Finally, since the rate methodology for general hospital clinics is determined by dividing costs by visits in a base year, and then this rate (subject to a legislative cap) is multiplied by each "visit" in the rate year, if OMIG were to disallow visits in a rate year that were not included in the base year, then it would be applying non-comparable factors, which would be arbitrary. Similarly, if OMIG were to insist now that certain tests which DOH has previously allowed clinics to bill as "ordered ambulatory" are instead part of a "visit," it would be acting arbitrarily because the per visit rate was not designed to include ordered ambulatory services, since the cost of those services are not in the base year costs.

III. New York Law on Hospital Outpatient Clinic Visits

A. Statute

The Public Health Law establishes the basic methodology for reimbursing hospitals for services to outpatients in hospital clinics. *See* Public Health Law § 2807(2)(g)(i).[1] It provides for a cost-based rate, with the operating component of the rate calculated as a cost per visit,[2] using allowable costs from a base year which is two years prior to the rate year. The operating component of the rate has been subject to a legislative cap of $67.50 per visit since 1991.

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[1] This section of the Public Health Law provides: "During the period April first, nineteen hundred ninety-four through December thirty-first, nineteen hundred ninety-four and for each calendar year rate period commencing on January first thereafter, rates of payment by governmental agencies for the operating cost component of general hospital outpatient services shall be based on the operating costs reported in the base year cost report adjusted by the trend factor applicable to the general hospital in which the services were provided; provided, however, that the maximum payment for the operating cost component of outpatient services shall be sixty-seven dollars and fifty cents plus the addition of the capital *cost per visit*." Public Health Law § 2807(2)(g)(i).

[2] Although the statute does not expressly state that the operating portion of hospital outpatient clinic rates shall be calculated on the basis of cost per visit (subject to the legislative cap), the express language discussing the addition of a capital cost per visit suggests that this is what the statute requires. This is the methodology DOH has traditionally used.

The statute contains no language suggesting that this rate is an "all-inclusive rate." Instead, it is a cost-based rate. One key issue, then, is what costs are included in the base. A second key issue is what is meant by the term "visit," which is not defined by the statute.[3]

B. Existing DOH Regulations

Below, we identify and describe the DOH regulations that are currently applicable to general hospital clinic visits (§ 86-1.11(h)(1) and Part 441), as well as certain of those regulations that are not applicable to general hospital outpatient clinic visits (§ 86-1.11(h)(3)-(4) and Subpart 86-4).

1. Regulation Relied on by OMIG: (Section 86-4.9)

It is noteworthy that the only regulation cited by OMIG in support of this audit is Section 86-4.9 of the Department of Health ("DOH") regulations, which defines a "threshold visit." As we explain below, Subpart 86-4 is not applicable to general hospital outpatient clinics.

a. Section 86-4.2(a) states that subpart 86-4 is applicable only to rates for "facility services." Section 86-4.1(a) defines "facility" to mean all "*freestanding* ambulatory care facilities, diagnostic and /or treatment centers and clinics that are subject to article 28...." Section 86-4.1(b) defines a "freestanding ambulatory care facility, diagnostic and /or treatment center and clinic" to mean a medical facility that is "not part of an inpatient hospital facility."

b. Therefore, section 86-4.9, which addresses "threshold visits," is not by its own terms applicable to visits in general hospital outpatient clinics. [4]

Portions of Subpart 86-4 are applicable to certain specialty hospital clinics pursuant to Section 86-1.11(h)(3) - (4). These subsections of 86-1.11(h) expressly prescribe that those types of specialty clinics (PCAP and Preferred Primary Care Providers) are to be reimbursed pursuant to specified subsections of Subpart 86-4 (§§ 86-4.36 and 86-

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[3] This term is defined in regulations relating to hospital cost reporting at 10 N.Y.C.R.R. § 411.339.

[4] Moreover, even where this regulation is applicable (for example to free-standing clinics), it does not support packaging ancillary services rendered by outside providers. With respect to ancillary services provided by the clinic itself, there are only limited circumstances in which that regulation supports including in the visit any ancillary services rendered after the date of the threshold visit. *See* arguments presented below in section IV.A.

4.37, respectively, which are discussed below in section 3). However, as we describe in section 2 below, general hospital clinics are reimbursed pursuant to section 86-1.11(h)(1) of the DOH regulations, which - in contrast to the provisions in 86-1.11(h)(3)-(4) - does not incorporate by reference any of the provisions of Subpart 86-4.

2. Regulations applicable to General Hospital Outpatient Clinics: § 86-1.11(h)(1), Parts 441 and 446.

a. Summary: No existing DOH regulations require a general hospital outpatient clinic to provide or arrange for a specific set of services. Thus, the base year costs included in calculating the payment rate do not include the costs of ancillary services provided by outside providers. Moreover, unlike the specialty clinics discussed in section 3 below, the payment rate for a general hospital clinic does not package ancillary services ordered during and provided after the date of a visit.

b. Licensure: Hospitals must receive CON approval to operate outpatient clinics. The CON approval sets forth the scope of services to be provided by each outpatient hospital clinic, which services are listed on the operating certificate of the hospital clinic. Different clinics may provide a different scope of services. (10 NYCRR Part 710.)

c. Operating Regulations: DOH sets forth the operating requirements for hospital outpatient services in 10 N.Y.C.R.R. § 405.20. This regulation does not require that hospitals provide or arrange for all services that a registered outpatient may require. Instead, this regulation requires that " The hospital shall effectively meet outpatient patient care needs by: ...(2) the appropriate *referral* to other health care facilities or health care practitioners for services not available....." 10 N.Y.C.R.R. § 405.20(c)(2) (Emphasis added).

d. Reimbursement Regulations: § 86-1.11(h)(1), Parts 441 and 446

(i) Rate Methodology. "Reimbursement rates for emergency and clinic outpatient services shall be computed in accordance with article 28 of the Public Health Law." § 86-1.11(h)(1). As we have noted in our discussion of the statute above, the rate methodology required by the statute is a cost-based rate, using costs from a base year two years earlier, divided by "visits." The operating component of the rate is subject to a legislatively imposed cap of $67.50.

(ii) Base Year Costs. Because the operating regulations and reimbursement regulations do not require the hospital to provide or arrange for all ancillary

services that a clinic patient may require, the costs of tests provided by outside facilities and physician offices are not in base year costs and therefore not included in the rate. *See, e.g.,* 10 N.Y.C.R.R. Part 446 (Reporting Requirements), including §§ 446.20, 446.23(b).

(iii) Visits. The regulations in Part 441 set forth the definitions hospitals are required to use in completing their cost reports for submission to DOH. Part 441 defines a "visit" as follows:

> "The physical appearance of an outpatient at a hospital complex is recognized as contributing one visit regardless of the number of diagnostic and/or therapeutic services the patient receives or the number of sections (clinics), operating rooms, laboratories and treatment areas in which he/she receives them. The classification of the visit (i.e., emergency, clinic, etc.) will be determined by the first location where service is rendered. 10 N.Y.C.R.R. § 441.339.

(iv) Ordered Ambulatory Services. In its definition of a "visit," Part 441 distinguishes what is to be considered "referred ambulatory" (now known as "ordered ambulatory") and, therefore, not to be counted as a clinic "visit:"

> *A patient referred from a physician's office exclusively for a specific ancillary service or services is classified as one referred ambulatory visit. A laboratory examination of a specimen sent in by a physician for his/her patient shall be included as one referred ambulatory visit.*" (Emphasis added.) 10 N.Y.C.R.R. § 441.339.

See discussion below in Section VI relating to Ordered Ambulatory Services.

(v) Other Definitions. *See* 10 N.Y.C.R.R. Part 441.[5]

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[5] § 441.30 - "Ambulatory services. The essential characteristic of ambulatory services is that the patients come to or are brought to a facility of the hospital for a purpose other than admission as an inpatient. Ambulatory services include emergency services, clinical services, ambulance services and home health services, but *exclude ancillary services*." (Emphasis added.)

§ 441.32 - "Ancillary Services" - These services are defined as "diagnostic or therapeutic services" performed by specific facility departments. "Ancillary services generally are those special services for which charges are customarily made in addition to routine charges and include such services as laboratory, radiology....."

e. Summary. As we have noted above, the current regulations applicable to general hospital outpatient clinics do not require a hospital to arrange for all ancillary services required by a clinic patient or expressly package ancillary services provided after the date of a visit into the clinic rate.[6] This is in stark contrast to the regulations applicable to specialty clinics, such as those serving PCAP patients or designated as Preferred Primary Care Providers, which expressly package ancillary services into a rate established by waiving the general hospital clinic cap. (Compare § 86-1.11(h)(1) applicable to general hospital outpatient clinics to § 86-1.11(h)(3)-(4), applicable to PCAP and to Preferred Primary Care Program, which incorporate by reference particular provisions of Subpart 86-4, including §§ 86-4.36 and 86-4.37, which we discuss below.)

3. Specialty Hospital Clinic Regulations

The DOH regulations in section 86-1.11(h)(3) and (4) list certain specialty hospital clinics that are subject to reimbursement provisions that are different from those applicable to general hospital clinics (which - as we have seen above - are subject to 86-1.11(h)(1)). The regulations in section 86-1.11(h)(3) and (4) governing these specialty hospital clinics expressly provide that they are to be reimbursed pursuant to particular provisions of Subpart 86-4, listed below:

- § 86-1.11(h)(3) expressly provides that reimbursement for the Prenatal Care Assistance Program ("PCAP") shall be computed in accordance with § 86-4.36, and

- § 86-1.11(h)(4) expressly provides that reimbursement for clinics designated as Preferred Primary Care Providers shall be computed in accordance with § 86-4.37.

Moreover, the DOH regulations on these specialty clinics (PCAP and Preferred Primary Care Providers) each explicitly package ancillary services into the rates paid for those clinic visits and - pursuant to PHL § 2807(11)- waive the legislative cap on

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[6] The Policy Guideline Manual of Article 28 Certified Clinics (Version 2007-2; June 1, 2007) applies to general hospital outpatient clinics the definition of a threshold visit set forth in § 86-4.9(b), which by regulation is applicable only to freestanding clinics. As we discuss below in section IV.A., even the definition in § 86-4.9(b) only packages the ancillary services provided by the hospital on the same day as the date of the threshold visit.

To the extent that this manual contains any language suggesting that ancillary services provided after the date of the threshold visit may be packaged with the visit, it is inconsistent with the regulation and arbitrary and capricious. In this connection, the manual was adopted without notice and comment rulemaking, and does not have the force of a law or regulation.

general hospital outpatient clinic rates established in PHL § 2807(2)(g)(i). Thus, DOH knows how to say that ancillary services are to be packaged into a single price if it intends to do so. Moreover, where it has done so, it has waived the clinic cap and established a higher rate, in recognition of the fact that the rate is expected to cover a larger package of services, including ancillary services.

a. Prenatal Care Assistance Program ("PCAP").

The PCAP program was adopted pursuant to L. 1989, c. 584. The reimbursement regulations governing the PCAP program were adopted pursuant to PHL § 2807(11), which authorizes DOH to waive otherwise applicable reimbursement provisions (i.e. the reimbursement provisions applicable to general hospital clinics). *See* NYS Register Jan. 17, 1990 at pp. 8-9. *See also* Public Health Law Article 25.

The regulations governing reimbursement for PCAP are set forth in § 86-1.11(h)(3), which provides that reimbursement shall be computed in accordance with § 86-4.36. The regulations in § 86-4.36 explicitly provide that the price established for the service includes payment for all ancillary services. Thus, section 86-4.36(d)(4) provides: "*The prices established pursuant to this section shall provide reimbursement for the following: ....(4) all ancillary services including laboratory tests and diagnostic x-ray services where specified in the treatment regimes and as detailed in the agreement pursuant to subdivision (b) of this section...*" 10 NYCRR §§ 86-4.36(d)(4) (Emphasis added). The regulation further specifies three types of clinic services that may be billed, all of which expressly include certain laboratory tests. *See* 10 NYCRR § 86-4.36(c). Pursuant to section 85.40 of the DOH regulations, PCAP providers are required to be responsible for providing or arranging for ancillary services required by PCAP patients, including laboratory and radiology testing services. *See* 10 NYCRR §§ 85.40(i)(1), 85.40(i)(3), and 85.40(b)(5)(iii).

Thus, DOH knows how to say that a provider is responsible for providing and arranging for certain ancillary services and that such ancillary services are to be packaged into a single price if it intends to do so. Moreover, where DOH has required providers to provide or arrange for a package of ancillary services, it has waived the clinic cap and established a higher rate, in recognition of the fact that the rate is expected to cover such packaged services.

b. Preferred Primary Care Program.

(i) Statute: PHL § 2807(2)(h).

"During the initial rate period such rates of payment for preferred primary care providers shall be at least equal to the average rate of payment per visit which would otherwise be provided pursuant to subparagraph (i) of paragraph (g) or paragraph (b) of this subdivision. *Factors used to establish rates shall include a reasonable classification of medical procedures with individual or combined rates established for each service classification group* which will be prospectively determined based upon an estimate of the costs of such outpatient services efficiently and economically provided by general hospitals and diagnostic and treatment centers, considering regional economic factors and the need for incentives to improve services and institute economies." (Emphasis added.)

(ii) Regulations: § 86-1.11(h)(4) provides:

"Payment rates for certain outpatient clinic services provided to Medicaid patients by diagnostic and treatment centers and by hospital based outpatient clinics designated as preferred primary care providers or as specialty services, shall be computed under the method used to compute rates as set forth in section 86-4.37, 86-4.38 or 86-4.39 of this Part, as appropriate." Section 86-4.37(d)(3) provides that the prices established pursuant to this program include all ancillary services " as detailed in the agreement described in subdivision (b)" which is an agreement between the provider and the commissioner of health. In addition, the regulation states that the services to be provided pursuant to the agreement include: "diagnostic examinations, treatments, and ancillary services including significant diagnostic technologies. Diagnostic technologies are defined as: diagnostic nuclear medicine, diagnostic radiology, diagnostic ultrasound, cardiography, cardiac fluoroscopy, echocardiography, and neurological and neuromuscular procedures." 10 NYCRR § 86-4.37(b).

In the preamble to the rulemaking establishing the regulation setting forth the rate methodology for preferred primary care clinics, DOH recognized that this methodology was an alternative to and a departure from the usual methodology for reimbursing for general hospital outpatient clinic visits. *See* NYS Register Oct. 17, 1990 at pp. 19-20 (proposed regulation) and January 22, 1991 at pp. 3-4 (final regulation). Thus, in the preamble to the original final rule, DOH stated:

> "The proposed amendments to Subpart 86-4 ...provides the Commissioner of Health the authority to create a prospective price based reimbursement methodology for outpatient ambulatory care services provided by licensed freestanding diagnostic and treatment centers and hospital based outpatient clinics designated as preferred primary care providers; and also the authority to set rates of payment for specialty services....New sections 86-4.37 and 86-4.38 create an *alternate payment methodology* for ambulatory care services provided to Medicaid recipients. Under this methodology, a set of twenty-four regionally adjusted prices for discrete clinic services are established." NYS Register (January 22, 1991) at pp. 3 (Emphasis added).

In adopting this alternative payment system for clinics designated as preferred primary care providers, DOH waived the $67.50 cap on the operating cost per visit applicable to general hospital outpatient clinics and established different payment rates. The PACs rates have been frozen since 1995 pursuant to L. 1995, c. 81, § 4., as most recently amended by L. 2007, c. 58, § 76.

Moreover, when DOH amended these regulations in 1991 to substitute 71 regionally adjusted prices (known as products of ambulatory care or "PACS"), it included the following language in the preamble to the proposed rule (in discussing the "Costs to private regulatory parties"):

> "Depending upon the existing service delivery structure at the participating provider's site, *certain requirements such as contracted laboratory and ancillary services may result in additional costs. However, these costs are recognized in the payment levels.* Participating providers should incur minimal net additional costs as a result of these regulations." NYS Register (October 16, 1991) at p. 19 (Emphasis added).

Thus, DOH knows how to say that a provider is responsible for providing and arranging for certain ancillary services and that such ancillary services are to be packaged into a single price if it intends to do so. Moreover, where DOH has required providers to provide or arrange for a package of ancillary services, it has waived the clinic cap and established a higher rate, in recognition of the fact that the rate is expected to cover such packaged services.

4. Proposed DOH Regulations in new Subpart 86-8.

In stark contrast to the existing regulations governing general hospital outpatient clinic rates (in § 86-1.11(h)(1)), DOH recently proposed new regulations in Subpart 86-8 that would package routine ancillary services into the payment rate for general hospital outpatient clinics as well as DTCs. *See* NYS Register September 3, 2008 at pp. 10 -14 (HLT-36-08-00033-P). [7] This regulation was proposed pursuant to Public Health Law § 2807(2-a)(e), enacted by L. 2008, c. 58, Part C, § 18, as amended by L. 2008, c. 53, Part OO, § 19. That law "notwithstands" the rate methodology otherwise required by Public Health Law § 2807((2)(g)(i), and authorizes DOH to adopt regulations utilizing a methodology based on ambulatory patient groups ("APGs"), which "may also utilize bundling, packaging and discounting." Public Health Law § 2807(2-a)(e).

The preamble to the proposed new Subpart 86-8 describes the reason that DOH decided on this new methodology rather than other alternatives as follows:

> "The Executive Budget ultimately advanced a proposal to implement the APG methodology because it is comprehensive, covers all medical outpatient services, reimburses based on patients' conditions and severity, and bundles the cost of ancillary services (e.g.: laboratory testing) and procedures into the overall payment."

Moreover, even the new proposed regulation would only package "routine" ancillary services. Thus, the proposed regulation includes the following definition: "Packaging shall mean those circumstances in which payment for *routine* ancillary services or drugs shall be deemed to be included in the applicable APG payment for a related significant procedure or medical visit." Proposed 10 NYCRR § 86-8.2(k) (Emphasis added). The proposed regulations would not package tests such as PET scans, which the OMIG Letter seeks to disallow.[8]

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[7] The preamble to the rulemaking recognizes that one way in which the methodology is new is that it would establish a "*uniform* reimbursement methodology for all ambulatory care services provided by hospital outpatient departments (including emergency and ambulatory surgery departments) and diagnostic and treatment centers (DTCs), also known as free-standing clinics..." NYS Register September 3, 2008 at p. 12. In so stating, DOH recognizes that, at the present time, the rate methodology for hospital clinics and DTCs is not uniform.

[8] In this connection, Medicaid allows hospital clinics to bill for MRI scans on a fee-for-service basis under a fee schedule, and excludes tham from the clinic rate. *See* Medicaid update dated May, 2002. It is unreasonable for Medicaid to not apply the same to PET scans and other tests whose cost vastly exceeds the capped clinic rate. We note that under the proposed regulations, tests such as MRI and PET scans are not packaged into the APG for medical visits as a routine test, and are instead assigned their own APG.

IV. Other DOH Regulations

A. Freestanding Clinic Rates - Subpart 86-4.

Freestanding clinics, known as diagnostic and/or treatment centers ("DTCs"), are currently reimbursed for their operating costs using a formula that divides allowable base year costs by allowable base year visits, subject to a cap determined using peer group costs. There is no statutory cap on this cost/visit rate, but the rates have been frozen since 1995. L. 1995, c. 81, § 4, as most recently amended by L. 2007, c. 58, § 76. This rate is payable to the DTC each time a patient incurs a "threshold visit." Generally, the DTC rates are higher than the rates for general hospital outpatient clinics, which have been legislatively capped since 1991 at $67.50.

1. Threshold Visit definition - § 86-4.9(b).

The regulations applicable to DTCs contain the definition of a "threshold visit" on which OMIG relied in its audit. *See* OMIG Letter. Even this definition, however, does not support packaging ancillary services provided by the hospital to clinic patients after the date of the threshold visit. Instead, it provides that "A threshold visit...shall occur each time a patient crosses the threshold...Only one threshold visit per patient per day shall be allowable for reimbursement purposes...."[9] 10 NYCRR § 86-4.9(b).

In this connection, it is useful to contrast the definition of a "threshold visit" in section 86-4.9(b) with the definition of a "procedure" in section 86-4.9(d). "A procedure shall include the total service, including the initial visit, preparatory visits, the actual procedure and follow-up visits related to the procedure. All visits related to a procedure, regardless of number, shall be part of one procedure and shall not be reported as a threshold visit." 10 NYCRR § 86-4.9(d). Thus, a procedure, in contrast to a threshold visit, expressly includes services provided before and after the date of the actual procedure.

2. Ordered Ambulatory Services - - § 86-4.9(f).

The regulations applicable to DTCs include the following definition of "Ordered Ambulatory Services:"

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[9] The entire definition is as follows: "A threshold visit, including all part-time clinic visits, shall occur each time a patient crosses the threshold of a facility to receive medical care without regard to the number of services provided during that visit. Only one threshold visit per patient per day shall be allowable for reimbursement purposes, except for transfusion services to hemophiliacs, in which case each transfusion visit shall constitute an allowable threshold visit." 10 NYCRR § 86-4.9(b).

> "Ordered ambulatory services may be covered and reimbursed on a fee-for-service basis in accordance with the State medical fee schedule. Ordered ambulatory services are specific services provided to nonregistered clinic patients at the facility, upon the order and referral of a physician, physician's assistant, dentist or podiatrist who is not employed by or under contract with the clinic, to test, diagnose or treat the patient. Ordered ambulatory services include laboratory services, diagnostic radiology services, pharmacy services, ultrasound services, rehabilitation therapy, diagnostic services and psychological evaluation services." 10 NYCRR § 86-4.9(f).

3. Allowable Costs.

The allowable costs of freestanding clinics do not include the costs of "ordered ambulatory" services. 10 NYCRR § 86-4.21(n). In addition, freestanding clinics are not responsible for ancillary services provided by other entities, since clinics are not required to provide or arrange for ancillary services and, therefore, the costs of ancillary services provided by other entities are not in the base year costs used to calculate the clinic rate. *See, e.g.* 10 NYCRR §§ 752-1.3 and 752-1.4.

B. Hospital Inpatient Rates

In contrast to the existing DOH regulations governing general hospital outpatient clinic services, the DOH regulations governing inpatient hospital services - like the Medicare regulations governing such inpatient services - do: (1) make hospitals responsible for providing or arranging for ancillary services for inpatients and (2) bundle ancillary services into an all-inclusive prospective payment rate based on diagnosis related groups ("DRGs") that was calculated on the assumption that ancillary services would be bundled into the rate. *See,e.g.,* 10 NYCRR § 86-1.52(a)(1)(ii). Thus, once again, DOH knows how to say that ancillary services are bundled into an all-inclusive rate if it intends to establish such a rate.

V. Medicare Regulations on Hospital Outpatient PPS

A. Original Proposed Regulations (1988)

Medicare originally proposed to require a hospital to provide or arrange for all diagnostic services ordered during a hospital outpatient visit and not allow separate billing for such tests even by outside providers. *See* 53 Fed. Reg. 29486 (Aug. 5, 1988), proposed 42 CFR §§ 405.310(n)(2)(ii) and 410.30.

B. Original Final Regulations (2000)

1. CMS subsequently dropped this proposal (that diagnostic tests ordered during a clinic visit and performed outside the hospital be bundled into the visit) and did not include it in the proposed or final rules published in 1998 or 2000. *See* 63 Fed. Reg. 47552 (Sept. 8, 1998) and 65 Fed. Reg. 18433 (April 7, 2000).

2. Among the reasons given by CMS for dropping this proposal were the following:

> "In §410.30(a) and (b) (now §410.39(a) and (b) of regulations published on August 5, 1988), we proposed to require the hospital to furnish directly or under arrangements all services furnished to its outpatient during an encounter as well as any diagnostic services furnished outside the hospital that were ordered during or as a result of an encounter in the hospital. *In this rule, we are not extending the bundling requirements to include diagnostic services ordered during an encounter in the hospital that are furnished outside the hospital. Thus, the hospital will not be required to furnish such diagnostic services directly or under arrangements. We are proposing a more limited approach to bundling because the PPS we are proposing involves less "packaging" than we anticipated when we published the August 1988 proposed regulations.* At that time, we believed that a PPS payment for a surgical procedure was likely to include preoperative tests and that payment for a clinic visit was likely to include the ancillary services (for example, laboratory tests and x-rays) that were needed to make a diagnosis. Therefore, by requiring bundling of off-site diagnostic tests that were ordered during an outpatient encounter at the hospital, we believed we could ensure that: (1) We had sufficient data to set payment rates that included the ancillary tests, and (2) once the system was implemented, the bundling rules would prevent any duplication of program payments. That is, a service packaged into a PPS payment to the hospital could not also be billed to the program as an ancillary test by an outside entity."
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> "*As noted above, the PPS we are proposing now does not include extensive packaging; therefore, the payment for related diagnostic tests is not included in the payments under the ambulatory payment*

classification (APC) groups for surgical procedures, clinic visits, emergency room visits, etc. Any diagnostic tests that are furnished will result in a separate payment. The program will pay the entity that actually furnishes the service --the hospital, if the service is provided directly or under arrangements made by the hospital; or another Medicare recognized entity, if the patient leaves the hospital and obtains the service elsewhere. Because diagnostic tests are not being packaged into another hospital service, we no longer need to require that a hospital furnish directly or under arrangements the services ordered during, or as a result of, an encounter, but furnished outside the hospital. If the PPS is changed in future years to require a more packaged approach to payment, the bundling regulations will be revised."

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"We are eliminating proposed §405.310(n). That section, which had described the hospital outpatient services that were excluded from coverage if not furnished directly or under arrangements, has been revised so that we will not require that hospitals bundle diagnostic services ordered during or as a result of an encounter in the hospital if furnished outside the hospital." 63 Fed. Reg. 47552 (Sept. 8, 1998) (Emphasis added.)

VI. New York Law on "Ordered Ambulatory" Services.

A. Existing DOH regulations

1. Rate Methodology: 10 NYCRR § 86-1.11(j): "Effective July 1, 1970, payments to hospitals for services to referred ambulatory patients shall be on a *fee-for-service* basis in accordance with the State fee schedules promulgated for the appropriate service." In other words, reimbursement for services to what used to be known as "referred ambulatory" patients, and which are now known as "ordered ambulatory" patients, are not paid as a clinic visit and such services are not included in a clinic visit. Indeed, the cost reporting regulations require reporting the statistics for "Private (Referred) Ambulatory Patients" separately from those of "Outpatient Department Visits by Clinic." *See* 10 NYCRR § 446.23(b) and (e).

2. Definitions:

Referred Ambulatory Visit - As we have noted above, Part 441, which contains the definitions applicable to services provided by a hospital, includes in the