NEW HEALTH CARE ACT REMOVES LEGAL JUSTIFICATION FOR MOST FNCS CONCIERGE PRACTICES

By

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1. Introduction

The largest segment of the concierge medicine industry is now almost ten years old. The legal foundation on which it is based was laid in 2002, when Tommy Thompson, the then-secretary of Health and Human Services, formally concluded that physicians who participate in Medicare could nonetheless charge patients a special fee in exchange for services that are not covered by Medicare, even when the fee amounts to a precondition to providing Medicare-covered services to those patients.[1]

Since 2002, these so-called "fee for non-covered services" ("FNCS") concierge practices have proliferated across the country to the point where one estimate puts the number of physicians practicing this form of medicine in the thousands.[2] While over the years there have been periodic threats to the legal validity of these practices, none has been as great as that created in March of last year with the enactment of the *Patient Protection and Affordable Care Act* (the "Act")[3]. It is not unreasonable to conclude, as the author has, that the challenge presented by the Act is so great as to remove the remaining legal validity of most FNCS concierge practices.

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[1] For more on the Thompson letter and its historical context, see the author's article: "Legal Issues Involved in Concierge Medical Practices," www.wnj.com/concierge_practices_jrm_3_2005/.

[2] One blogger suggested that there are about 5,000 concierge physicians operating in the United States. www.managemypractice.com. He does not cite his source for this, but the suggestion is most certainly inflated, by a lot. The authors of a March of 2010, MedPAC report ("Retainer-Based Physicians: Characteristics, Impact, and Policy Considerations") (see www.medpac.gov) could find fewer than 800 such practices, although they acknowledged that their number would likely be the lower limit of the actual one.

[3] Public Law No. 111-148, March 10, 2010.

2. The Problem

It has been customary for these FNCS practices to provide a patient with an annual "wellness" physical exam, which is normally accompanied by the development of some form of wellness or health plan for the ensuing year. In addition, the typical FNCS patient contract includes around-the-clock direct phone or pager contact with the physician, no wait appointments, same day or next day appointments, and e-mail access.

Congressman Henry Waxman (D-Cal) and five of his colleagues initiated the 2002 controversy by complaining to Secretary Thompson that concierge practices were charging patients a special fee for services already covered by Medicare and were making the payment of the fee a precondition to rendering Medicare services.[4] Secretary Thompson disposed of this latter issue by his oblique statement that "physicians have some discretion regarding the patients they choose to accept." Since then there has not been anything written about this "precondition" issue, and it seems to have pretty much fallen by the wayside.

Secretary Thompson dealt with the main issue more directly by concluding that:

> While the limiting charge provisions govern physicians' charges for Medicare-covered services, these provisions do not directly affect charges for noncovered services. Insofar as the retainer under such an agreement is truly for noncovered services, such fees would not appear to be in violation of the Medicare law.

The Thompson letter then referred to a field memorandum issued just a few weeks before his letter by the Centers for Medicare & Medicaid Services (the "Field Memorandum"). The memorandum, which was also attached to the Thompson letter, instructed the agency's field agents on how to handle concierge practices. While not commenting on the specifics of the Waxman complaint, it did define the sort of practice with which the memorandum was concerned: practices that required an annual fee in exchange for which the patients "receive various services (such as an annual physical) or amenities (for example, same-day or next-day appointments)."

Several years ago it was conventional wisdom that Medicare did not cover so-called periodic wellness physicals. An otherwise healthy Medicare patient could not just have her physician give her an annual physical and expect Medicare to pay for it. It was quite simple, therefore, for a physician to charge a special fee for an "annual wellness physical" because it was just not covered by Medicare. The syllogism sustaining the legal justification for FNCS practices thus ran as follows: Wellness physicals are not covered by Medicare; a physician can legally charge a special fee for medical services that are not covered by Medicare; therefore, a physician can legally charge a special fee for wellness physicals. The Act fundamentally changes the syllogism's major premise.

[4] Patients around that time had complained that physicians converting their practices to the FNCS concierge model were requiring them to pay an annual lump-sum fee or find another physician.

3. Administrative Attitude

An important element in assessing the impact the new Act will have on FNCS practices is an appreciation of the federal government's historical attitude toward them, starting with Secretary Thompson's letter itself. For instance, it would be an error to conclude that the Thompson letter was a clear and ringing endorsement of this form of medical practice. While the letter has served for almost a decade as the only legal authority for them (at least insofar as Medicare is concerned[5]), it was somewhat reserved in affirming the essential FNCS concept. While generally giving physicians the go-ahead, Thompson cautioned that they "are responsible for complying with applicable Medicare requirements" and that his office "…will continue to monitor the situation carefully – especially for any evidence of coercive activity relating to such agreements – and consider whether any further steps are indicated."

While the Field Memorandum was, of course, consistent with the Thompson letter, it was nonetheless obtuse, if not outright cagey, as to how far the basic FNCS concept could be taken. It warned that "the structure of these [patient] agreements present certain legal concerns" and then instructed the agents not to give any physician in the field guidance as to the question of legality (the agent should "neither approve or [sic] disapprove" of the practices). Finally, the agents should warn the physicians that if they were contemplating forming such a practice they should "seek legal counsel to ensure the agreements comply with the law."

If we left 2002 with a semblance of guarded clarity as to the legality of FNCS concierge practices, it was not too long until CMS, speaking through its enforcement arm, the Office of Inspector General (the "OIG"), injected considerable uncertainly into the issue. In 2004, it issued a fraud alert[6] that seemingly was designed not only to cast doubt on the validity of the Thompson conclusion but intentionally to obscure the legal status of concierge practices. The Alert dealt with a physician in Minneapolis who had agreed to pay a significant fine and step out of Medicare for a number of years for doing something wrong in operating a concierge practice. While what this physician was doing was clearly a problem[7] even within the confines of the four corners of the Thompson letter, the OIG chose not to explain the case by reference to that one thing. Instead, it proceeded to list three things the physician was doing and, in an apparent effort to keep everyone guessing, warned us that "some of them are covered by Medicare."

Probably because the facts of this case were somewhat on the egregious side, nothing much was done to apply the case to other situations. Then in 2007, along came the more

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[5] There is also an issue whether FNCS practices square with the provisions of private contracts between physicians and insurance companies. These issues are not uniform from insurance company to insurance company and are not, in terms of their effect on physicians, as daunting as those presented by Medicare.

[6] See the author's article *The Politics of Concierge Medicine; the Vulnerability of the FNCS Model*, www.wnj.com/politics_of_concierge_medicine_jrm_article/) for a more in-depth treatment of the Fraud Alert.

[7] The physician agreed to waive the patient's co-pays in exchange for the annual fee.

troubling Rocomora case. This case involved a North Carolina physician running what appeared to be a fairly standard FNCS practice. Here is how CMS describes the case on its website:

> Lee R. Rocamora, M.D., North Carolina, agreed to pay $106,600 to resolve his liability for allegedly violating the Civil Monetary Penalties Law. The OIG alleged that the practitioner requested payments from Medicare beneficiaries in violation of his assignment agreement. Specifically, the practitioner allegedly asked his patients to enter into a membership agreement for his patient care program, under which the patients paid an annual fee. In exchange for the fee, the membership agreement specified that the practitioner would provide members with: (1) an annual comprehensive physical examination; (2) same day or next day appointments; (3) support personnel dedicated exclusively to members; (4) 24 hours a day and 7 days a week physician availability; (5) prescription facilitation; (6) coordination of referrals and expedited referrals, if medically necessary; and (7) other service amenities as determined by the practitioner.

Note that this practice sounds a lot like the current standard FNCS practice, but again the OIG does not tell us what the doctor was actually doing wrong. The author filed a Freedom of Information Act Request with the OIG in hopes of finding out what the transgression actually was, but nothing much was furnished in response (other than Dr. Rocamora's patient agreement). The OIG therefore passed up another opportunity to inform the legal and medical communities whether it was applying new rules regarding concierge practices or whether the old rules were simply falling apart.

It is a reasonable conclusion to draw that the OIG and CMS are not particularly fond of concierge medicine. If that conclusion is accurate, it reinforces the concern that the provisions of the new Act may bring an end to FNCS practices that charge a special fee for annual wellness physicals.

4. The Dynamic

Notwithstanding the above, there is no real evidence that CMS or the OIG have changed their views regarding the continued merit of the Thompson rule or the legality generally of the FNCS form of concierge medicine. But there is plenty of evidence that the other part of the Thompson equation (that is, the services covered by Medicare) has changed significantly since 2002. In the years after 2004, Medicare began covering certain screening and preventive services, which in turn automatically reduced the number of things concierge physicians could offer in exchange for their special fee. To the extent a service or procedure that was typically performed as part of an annual wellness exam (for which a patient had paid a special fee) became covered by Medicare, then the physician automatically (and perhaps unknowingly) began charging a special fee for something that was covered by Medicare, and that was a clear violation of the Thompson rule.

The trend toward expanding Medicare coverage of preventive and screening services presented itself in several forms over the years,[8] the clearest example of which was the so-called *Welcome to Medicare Physical* created in 2005[9] (the "IPPE"). This presented a serious problem for concierge physicians, since the wellness exam preformed for the patient who paid the special fee arguably and suddenly became covered by Medicare. Initiated in January of 2005, the IPPE was originally available only during the first six months of the patient's Medicare coverage.[10] On January 1, 2007, the six-month period was extended to the entire first year of Medicare coverage.

Whatever solutions concierge physicians put in place to accommodate the new IPPE, they were at best imperfect. Most concierge physicians argued generally that their annual physical exams were much broader and more comprehensive than the simple IPPE, therefore taking them out of the Thomson rule. But in doing so they neglected to realize that taking a patient's blood pressure, for example, as part of a broad and comprehensive physical exam is pretty much the same as taking a patient's blood pressure as part of the briefest of wellness visits.

The new Act presents a much more fundamental problem for FNCS practices by creating a new Medicare-covered service called Personalized Preventive Plan Services, now being called by CMS simply the *Annual Wellness Visit* (the "AWV"). Unlike the IPPE, the AWV is by its very nature an annual service the patient can request of his physician, including his concierge physician.[11] The reason this presents a more significant problem is that it is one thing to contend with (accommodate) a one-time physical exam when a patient starts Medicare coverage; it is another to contend with (accommodate) essentially the same problem year after year for each Medicare patient in a practice. For example, one obvious solution to the IPPE problem was for the FNCS physician simply not to charge the new Medicare-covered patient the special fee for the year in which the patient was eligible for the IPPE. That simple solution is not available when the Medicare patient can have what amounts to a wellness physical every year.

If there is any doubt as to CMS's view of the current status of Medicare coverage for annual wellness exams, one need look no further than the content of Medicare's web site (see www.medicare.org/medicare-basics/part-b.html). CMS states here that:

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[8] See Charles B. Root, "New Medicare Preventive Services and Screening Tests You Can Perform in the Office," Medicare *Patient* Management, March/April 2006, page18, http://www.medicarepatientmanagement.com/issues/01-02/MPM01-02_Screening.pdf.

[9] The technical name for this physical exam is the Initial Preventive Physical Exam. See 42 USC 1395x(ww).

[10] This led some physicians to postpone any physical exam for a new Medicare patient until AFTER the six months of her Medicare coverage expired to ensure that the physical exam could not possibly be mistaken for the IPPE. Aside from the obvious ethical problems with this approach, as a practical matter this shenanigan was put to rest in 2007 when the eligibility for the IPPE was extended to the full year of a patient's Medicare coverage.

[11] There are no co-pays or deductibles associated with the AWV. Medicare pays 100%.

> *NEW FOR 2011. As part of the Affordable Care Act of 2010, Medicare now pays for most preventive services at no cost to you (no Part B deductible or coinsurance) if you get the services from a doctor or other health care provider who accepts Medicare assignment.*

Moreover, in a recent publication for new physicians[12] ("A Roadmap for New Physicians – Avoiding Medicare and Medicaid Fraud and Abuse") the OIG and CMS had this to say on page 14:

> You may see advertisements offering to help you convert your practice into a "boutique," "concierge," or "retainer" practice. Many such solicitations promise to help you work less, yet earn more money. If you are a participating or non-participating physician, you may not ask Medicare patients to pay a second time for services for which Medicare has already paid. It is legal to charge patients for services that are not covered by Medicare. However, charging an "access fee" or "administrative fee" that simply allows them to obtain Medicare-covered services from your practice constitutes double billing.

There are certainly ways to try to square the AWV with the existing law relating to concierge medicine. [13] But after having worked with many concierge physicians in the last six months regarding these issues and studying the AWV provisions, the author has come to believe that there is simply no clear way to accommodate the AWV within the Thompson rule. Here is why.

I looked at a random number of so-called executive physicals found on the Internet with an eye to isolating what might be a typical fulsome, expanded, and comprehensive physical exam (one like an FNCS physician might say she is giving to her concierge patients). A typical one is the *Mass General Executive Physical*, which includes the following:

(i) Medical History
(ii) Comprehensive Physical Exam*
(iii) Colorectal cancer screening
(iv) EKG
(v) Body Composition Analysis
(vi) Series of lab tests
(vii) Spirometry
(viii) Audiometry
(ix) Visual acuity
(x) Immunizations
(xi) Pap smear

[12] http://oig.hhs.gov/fraud/physicianeducation.

[13] See the author's article "Suggested Modifications to Fee for Non-Covered Services Concierge Practices as a Result of New Healthcare Act," http://www.wnj.com/suggested_modifications_to_fee_for_non-covered_services_concierge_practices_as_a_result_of_non_health_care_act-concierge_law/.

(xii) PSA

*Although not stated, one would assume that blood pressure, pulse, and the basics are covered.

Now look at the particulars of the AWV, as provided by the Act and by the new Rules issued pursuant to it[14]:

(i) Medical and Family History
(ii) List of current providers and suppliers to patient
(iii) Measurement of height, weight, body-mass, blood pressure, and other routine measurements
(iv) Detection of any cognitive impairment
(v) Review of risk factors for depression
(vi) Screening schedule for the next 5 to 10 years
(vii) List of risk factors for which primary, secondary, and tertiary interventions are recommended
(viii) Furnishing of personalized health advice

While these two exams are by no means identical, one cannot reasonably reach the conclusion that there is no significant overlap between them. The medical history, for instance, is identical. And the blood pressure and other standard measurements would certainly be included in the Mass General physical. It is not too much of a stretch to say that almost everything included in the AWV would be included in the Mass General Executive Physical in some form. And it is the case that virtually every component of the Mass General physical would be covered by Medicare if it were given to a Medicare-covered patient under certain circumstances.[15]

So, the issue is framed like this. A concierge physician accepts $2,000 from a patient in exchange for a comprehensive annual wellness physical exam and the normal amenities (24x7 personal physician contact, no wait appointments, same day appointments, etc.). If we are now in a position to assess whether this practice is violating the Thompson rule, what is our test? The test pretty clearly is whether the physician has accepted the $2,000 in exchange for something that is covered by Medicare. Is it possible to conclude that nothing the physician will do as part of the comprehensive annual physical is within the AWV list? Put another way, how is it possible for the physician to perform the comprehensive annual physical exam without performing many of the things that are within the AWV and now covered by Medicare?

[14] 75 Fed Register 73170-01, November 29, 2010.

[15] Some services listed would not be covered in an annual wellness context, at least every year, but some would be covered even in a wellness context in certain years and as part of a physical if medically indicated as part of an underlying diagnosis. A screening EKG, for instance, is covered by Medicare on a one-time basis, but an EKG is also covered in a non-screening context if indicated as part of a diagnosis and is medically indicated.

The essence of the OIG's 2004 Fraud Alert was the following, appearing on the second page:

> While the [Minneapolis] physician characterized the services to be provided under the contract as "not covered" by Medicare, the OIG alleged that at least some of these contracted services were already covered by Medicare. Among other services offered under this contract were the "coordination of care with other provider," "a comprehensive assessment and plan for optimum health," and "extra time" spent on patient care. OIG alleged that based on the specific facts and circumstances of this case, at least some of these contracted services were already covered and reimbursable by Medicare. (Emphasis added)

In face of this language, it is small comfort to assert that not all the physical exam services for which the patient pays the special fee are covered by Medicare all the time. The rule seems to be, as articulated in the Fraud Alert, that it is sufficient if just SOME of them are. Assuming this is the rule, for an FNCS physician to bring himself or herself within the protection of the Thompson rule, no part of the annual physical exam he or she is charging the special fee for could be covered by the AWV, a truly untenable position. Putting it in the words of the Fraud Alert: at least some of the elements of the annual wellness physical are already covered and reimbursable by Medicare as part of the AWV.

5. What Services Are Likely Still Safe?

While half the Thompson equation appears to have been obliterated by the new AWV for those FNCS practices offering an annual wellness physical, the reach of the Thompson letter was broader than a mere physical exam. Recall that the Waxman letter complained of a number of other services being offered by the physicians he described in his letter. The list included the following:

1. Same day and next day appointments
2. 24/7 direct physician contact[16]
3. E-mail and fax access to the physician's office
4. Prescription facilitation
5. Coordination of necessary referrals
6. Claims facilitation

[16] Some anti-concierge medicine public officials, like the New Jersey and New York health departments (for copies of the letters from these departments see www.wnj.com/practiceindustries/retainermed/legal_developments/), have suggested that physicians already, as a matter of course, give or are obligated to give their patients 24/7 access. Such a suggestion reveals a bias that is not supported by any real analysis or even much awareness. Very few non-concierge physicians expose themselves, personally, to 24/7 direct contact by patients. Certainly patients of most primary care physicians can "reach" their physician 24/7 by called an answering service, which then routes the patients to a covering physician, and maybe directly to the patients' actual physician if he or she happens to be on call. But that is much different than the patient paying the concierge physician a special fee in order to have direct 24/7 access to her physician at all times.

7. Travel medical services
8. Private reception area "replete with amenities"

Since neither the Field Memorandum nor the Thompson letter condemned any on this list, and since most of them are not medical services at all, there does not appear to be a good reason why a physician cannot charge a special fee for some of them.[17]

One approach for FNCS physicians who have historically offered an annual physical as part of their special fee could be to eliminate the physical altogether and instead include (or retain) some of the above "amenities" in the special fee.[18] The most typical would be 24/7direct physician phone access, same day/next day appointments, and e-mail access.[19] This may create a marketing problem for many practices, since eliminating (or not offering) the annual physical will reduce the value of what the FNCS physician is offering. On the other hand, the issue is one of legality, not economics. Moreover, a case can be made for adopting the practice of performing the physical, at the request of the patient, and billing as much of it as can be billed under Medicare and private insurance rules and charging the required co-pays and deductibles to the patient. This would put the billing for any periodic physical in accord with Medicare and private insurance billing requirements. Of course, if the physician includes in his or her annual physical items that are not covered by Medicare or private insurance, the patient is either going to have to pay for them out of pocket or the physician is not going to bill for them.

Some caution should be exercised in adopting one or more of the amenities, however, as Medicare may take the position that, even though there is no particular billing code for an item, some are still covered. For instance, the private reception area "replete with amenities" sounds very close to the general office overhead that Medicare already impliedly covers.

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[17] Nothing in this comment should be taken as legal advice. Any physician contemplating including one or more of these services in a patient agreement should consult his or her attorney.

[18] Another reason this result will be disappointing to many concierge physicians is its effect on efforts to inform patients that the special fee is an expense that can be paid from a Health Savings Account, another so-called "acronym plan" (like an FSA and MSA), or a cafeteria plan. Concierge physicians are notorious for jumping to conclusions as to the applicability of these plans to special concierge medicine fees. But this entire area is cloudy and uncertain and no one can be sure, under existing law, whether any part of a concierge fee can qualify for any of them. However, the chances they can qualify increase if the special fee is paid for medical care, like an annual physical. If only "amenities" are included in the special fee, then there is likely no chance the payments will qualify. A similar point can be made about whether the special fee can count toward a patient's deductible amount under a high-deductible health insurance policy.

[19] And there are others that would not likely trigger a Medicare problem because they are not medical services. For instance, some physicians include "friends and family" provision that allows friends and family visiting or vacationing with the concierge patient to have the same direct access to the physician for a limited number of days during the year.

6. Conclusion

While the new Annual Wellness Visit has likely spelled the end to most traditional FNCS concierge practices that include an annual wellness physical as part of their special fee, there is no reason why these practices cannot be reconfigured and continue to operate within the law. The Thompson principle that a physician may charge a patient a special fee for things that are not covered by Medicare is still viable and remains the law. Many services, mainly non-medical amenities or valuable attributes of a concierge practice, should continue to be the subject of special fees for FNCS practices.[20]

[20] Recall in footnote 12 the reference to the new CMS publication warning new physicians that charging an "'access fee' or 'administrative fee' that simply allows them to obtain Medicare-covered services from your practice" amounts to double billing. This reference to an "access" or "administrative" fee should not be taken as referring to providing the patient with something special that has value in the market place, like personal, direct, 24/7 coverage or friends and family access, things that a physician is not otherwise obligated (legally or ethically) to do for patients. The reference should be taken to mean those sorts of across-the-board charges that are little more than surcharges to patients just so they can continue to belong to a practice. There have been reports of physicians billing all their patients a small amount annually to help the physician with his or her overhead. Such charges are without much question illegal.

