NEW HEALTH CARE ACT DEALS SERIOUS BLOWS TO CONCIERGE MEDICINE

By

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I. Introduction

There are generally two types of concierge[1] medicine physician practices. In one, the physicians remain in Medicare and charge a periodic fee (usually on an annual basis)[2] to patients in exchange for services that are not covered by Medicare (or in most cases by private insurance). These are often called "FNCS" practices (an acronym for Fee for Non-Covered Services).

In the second type, the physician opts out of Medicare and then charges the patient a periodic fee for providing all the medical care the patient needs and that can be provided by the physician himself or herself. The physician's agreement is only to offer the medical care the physician himself or herself can provide – a family medicine physician only agrees to provide family medicine services, for instance, not orthopedic or other specialized care from other physicians. This is a major factor in what distinguishes these forms of practice from insurance.

In large part, HHS and its enforcement arms have left legitimate FNCS practices alone. But the Patient Protection and Affordable Care Act (the "Act")[3] is going to cause serious problems for these practices and will require them to restructure in order to accommodate the Act. The Act creates other problems for the fee-for-care model, problems that are not as fixable.

II. The FNCS Model

The FNCS model is based on the assumption that the annual fee paid to the physician is for services that are not covered by Medicare. This is to bring the practice within the primary legal authority for these kinds of practices: the 2002 one-page letter from Tommy Thompson,

[1] The author is not unmindful of the feeling among many that the word "concierge" is not an appropriate word to describe some kinds of practices, particularly those fee-for-care practices that charge very modest monthly fees. It is used here as a matter of convenience due to its secondary meaning, a meaning that is likely very familiar to almost all of the readers of this article. Many fee-for-care practices prefer to be known as "direct practices."

[2] Many FNCS physicians receive the annual fee at intervals throughout the year, like quarterly or even monthly. This article will assume that the physicians charge on an annual basis, as more frequent payment intervals do not affect the analysis presented here or the issues created by the Act.

[3] On March 20, 2010, President Obama signed the Patient Protection and Affordable Care Act, Public Law No. 111-148, along with the Health Care and Education Reconciliation Act of 2010 (Public Law No. 111-152), which contained a series of "fixes" to the original Bill passed by the House of Representatives and the Senate.

then Secretary of HHS. MDVIP, a Florida-based company and the largest national player in organizing such practices, was at the heart of the controversy leading up to the issuance of the Thompson letter. Congressman Waxman and others had asked Secretary Thompson to rule that these practices violated the Medicare statutes and to take enforcement action against them. He refused to do so and essentially blessed what MDVIP was doing.

Most FNCS practices (what can be called "classic" FNCS practices) provide for an annual physical examination and a personalized wellness or lifestyle plan for diet, exercise, and medications. These practices have assumed that most of the wellness and preventive services they provide are not covered by Medicare and can therefore provide them to the patient in exchange for the annual fee.[4] Over the years, however, more and more screening and preventive services have been added to Medicare's coverage, eroding the validity of this assumption. The Act has taken this to another level, where reliance on the assumption is simply no longer justified. Classic FNCS practices would be well-advised to restructure if they are to going to stay within the new law.[5]

(a) Expansion of Preventive Services

Section 4104 of the Act is entitled "Removal of Barriers to Preventive Services in Medicare" and adds a new paragraph to Section 1861(ddd) of the Social Security Act. This new paragraph establishes a general definition of "preventive services," which are now collectively defined as the sum (i) of the "welcome to Medicare physical" (or technically called the "initial preventive Medicare physical examination" (see Section 1861(ww)(1)), (ii) of a list of screening tests appearing in Section 1861(ww)(2), and (iii), most importantly, of something new called Personalized Preventive Plan Services (let's call them "3P Services").

The initial preventive Medicare physical examination is not new, nor is the list of screening tests, but the Act did change the wording of the statute. The covered physical is still a one-time thing, paid for by Medicare only if it is given during the first year of a patient's coverage under Medicare. What is new, and what is going to spell major trouble for these types of concierge practices, are the 3P Services.

The initial preventive Medicare physical has been around since 2005. It was first allowed during the first six months of a person's coverage under Medicare, and this was later expanded to the full year. Most concierge practices who offered an annual physical felt that the Medicare physical was so qualitatively different from the comprehensive annual physicals offered to concierge patients that the distinction between the two would be readily apparent. While that may have been legally true before the Act, the creation of the general definition of "preventive services," along with the specific expansion of screening services generally, make the risk of confusing a typical concierge-style comprehensive annual physical examination with the initial preventive Medicare examination far more likely.

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[4] The possibility of confusion in billing led some concierge physicians to refuse to give the patient a physical during his or her first six months of Medicare coverage. This would ensure that the physical given for that year, for which the patient paid, could not possibly be confused with the initial Medicare physical. Later the initial Medicare physical was expanded to encompass the entire year, which made this practice impossible.

[5] The effective date of these provisions of the Act is January 1, 2011.

(1) PPP Services

Section 1861(s) of the Social Security Act defines the health services that are covered by Medicare. Section 1861(s)(2)(W) includes the initial preventive physical. The Act amends this Section 1861(s) by inserting a new subsection (FF), which creates the concept of "personalized prevention plan services" and defines them to be Medicare-covered services.[6]

The Section of the Act that defines 3P Services is entitled *Annual Wellness Visit*, and indeed a Medicare patient is entitled to these services annually. Section (G)(i) provides that:

> "A beneficiary shall only be eligible to receive an initial preventive physical examination…at any time during the 12-month period after the date that…[his or her]…coverage begins…and shall be eligible to receive personalized preventive plan services…provided that…[he or she]…has not received such services within the preceding 12-month period."

Most classic FNCS practices include a wellness planning component as part of or after the annual physical examination. The issue to watch for in reviewing the provisions of the Act as to the 3P Services is the extent to which these classic annual wellness plans are now covered services. To the extent they are, FNCS practices are not going to be able to charge for them as part of their annual fee.

This Act (Section 4103) defines 3P Services as part of the creation of a plan for the Medicare patient that includes:

> …a health risk assessment (that meets the guidelines established by the Secretary under paragraph (4)(A)) of the individual that is completed prior to or as part of the same visit with a health professional described in paragraph (3); and that takes into account the results of the health risk assessment may contain the following elements:
>
> > (A) The establishment of, or an update to, the individual's medical and family history.
> >
> > (B) A list of current providers and suppliers that are regularly involved in providing medical care to the individual (including a list of all prescribed medications).
> >
> > (C) A measurement of height, weight, body mass index (or waist circumference, if appropriate), blood pressure, and other routine measurements.

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[6] Note that it will take at least a year, and likely longer, before this is all completely fleshed out, as the Secretary of HHS has one year to establish standards for providing PPPS. See the discussion at the bottom of the next page.

(D) Detection of any cognitive impairment.

(E) The establishment of, or an update to, the following:

(i) A screening schedule for the next 5 to 10 years, as appropriate, based on recommendations of the United States Preventive Services Task Force and the Advisory Committee on Immunization Practices, and the individual's health status, screening history, and age-appropriate preventive services covered under this title.

(ii) A list of risk factors and conditions for which primary, secondary, or tertiary prevention interventions are recommended or are underway, including any mental health conditions or any such risk factors or conditions that have been identified through an initial preventive physical examination (as described under subsection (ww)(1)), and a list of treatment options and their associated risks and benefits.

(F) The furnishing of personalized health advice and a referral, as appropriate, to health education or preventive counseling services or programs aimed at reducing identified risk factors and improving self management, or community-based lifestyle interventions to reduce health risks and promote self-management and wellness, including weight loss, physical activity, smoking cessation, fall prevention, and nutrition. (Emphasis added)

(G) Any other element determined appropriate by the Secretary. (Emphasis added)

If this list were not expansive enough without paragraph (F), paragraph (F) would encompass virtually any medical suggestions given to a patient as part of the 3P Services. It is hard to read the phrase "the furnishing of personalized health advice" any other way. That is pretty much done in all cases where a physician administers a physical examination or just meets with a patient and performs the most modest of assessment techniques. Much of what these classic practices do for patients as part of an annual wellness plan or assessment are going to fall within these 3P Services and therefore be covered by Medicare.

An additional difficulty for these classic FNCS practices is that the target is going to be moving. The Act (Section 4103) goes on to provide that :

For purposes of paragraph (1)(A), the Secretary, not later than 1 year after the date of enactment of this subsection, shall establish publicly available guidelines for health risk assessments. Such guidelines shall be developed in consultation with relevant groups and entities and shall provide that a health risk assessment—

(i) identify chronic diseases, injury risks, modifiable risk factors, and urgent health needs of the individual; and

(ii) may be furnished—

(I) through an interactive telephonic or web-based program that meets the standards established under subparagraph (B);

(II) during an encounter with a health care professional;

(III) through community-based prevention programs; or

(IV) through any other means the Secretary determines appropriate to maximize accessibility and ease of use by beneficiaries, while ensuring the privacy of such beneficiaries.

To the extent these practices try to accommodate the new Act too slavishly, they are going to have to keep an eye on whatever the Secretary does to expand the list of those things that are covered.

(2) The Moving Target

Section 4103 of the Act adds paragraph (G)(i) dealing with the annual physical and the 3P Services and reads in full as follows:

(G) (i) A beneficiary shall only be eligible to receive an initial preventive physical examination (as defined under subsection (ww)(1)) at any time during the 12-month period after the date that the beneficiary's coverage begins under part B and shall be eligible to receive personalized prevention plan services under this subsection provided that the beneficiary has not received such services within the preceding 12-month period.

(ii) The Secretary shall establish procedures to make beneficiaries aware of the option to select an initial preventive physical examination or personalized prevention plan services during the period of 12 months after the date that a beneficiary's coverage begins under part B, which shall include information regarding any relevant differences between such services.

(H) The Secretary shall issue guidance that—

(i) identifies elements under paragraph (2) that are required to be provided to a beneficiary as part of their first visit for personalized prevention plan services; and

(ii) establishes a yearly schedule for appropriate provision of such elements thereafter.[7]

[7] For anyone confused by what is included in the "initial preventive physical examination," here's what the existing Medicare law describes it to be [footnote continued on next page]:

Section 4003 of the Act recreates a national "Preventive Services Task Force (by amending 42 U.S.C. 299b-4). This provision requires the Director to convene an "independent" Task Force "to be composed of individuals with appropriate expertise" to "review the scientific evidence related to the effectiveness, appropriateness, and cost-effectiveness of clinical preventive services." It will then develop recommendations "for the health community" as to the effectiveness of certain preventive procedures.

Section 4105 of the Act is entitled "Evidence-Based Coverage of Preventive Services in Medicare." Section 4105(a) provides that Section 1834 of the Social Security Act is amended by adding the following paragraph (n):

> (n) AUTHORITY TO MODIFY OR ELIMINATE COVERAGE OF CERTAIN PREVENTIVE SERVICES.—Notwithstanding any other provision of this title, effective beginning on January 1, 2010 [this is now January 1, 2011] if the Secretary determines appropriate, the Secretary may
>
> (1) modify
>
> (A) the coverage of any preventive service described in subparagraph (A) of section 1861(ddd)(3) to the extent that such modification is consistent with the recommendations of the United States Preventive Services Task Force; and
>
> (B) the services included in the initial preventive physical examination described in sub paragraph (B) of such section; and

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(ww)

(1) The term "initial preventive physical examination" means physicians' services consisting of a physical examination (including measurement of height, weight, body mass index, and blood pressure) with the goal of health promotion and disease detection and includes education, counseling, and referral with respect to screening and other preventive services described in paragraph (2) and end-of-life planning (as defined in paragraph (3)) upon the agreement with the individual, but does not include clinical laboratory tests.

(2) The screening and other preventive services described in this paragraph include the following:

(A) Pneumococcal, influenza, and hepatitis B vaccine and administration under subsection (s)(10).
(B) Screening mammography as defined in subsection (jj).
(C) Screening pap smear and screening pelvic exam as defined in subsection (nn).
(D) Prostate cancer screening tests as defined in subsection (oo).
(E) Colorectal cancer screening tests as defined in subsection (pp).
(F) Diabetes outpatient self-management training services as defined in subsection (qq)(1).
(G) Bone mass measurement as defined in subsection (rr).
(H) Screening for glaucoma as defined in subsection (uu).
(I) Medical nutrition therapy services as defined in subsection (vv).
(J) Cardiovascular screening blood tests as defined in subsection (xx)(1).
(K) Diabetes screening tests as defined in subsection (yy).
(L) Ultrasound screening for abdominal aortic aneurysm as defined in section 1861(bbb).
(M) An electrocardiogram.
(N) Additional preventive services (as defined in subsection (ddd)(1)).

(2) provide that no payment shall be made under this title for a preventive service described in subparagraph (A) of such section that has not received a grade of A, B, C, or I by such Task Force.

We now have a situation where it is impossible to tell what services the Task Force may add to those that are covered or not covered by Medicare. What is not covered one day may be covered the next, and it will be virtually impossible for FCNS practices to keep pace. A fundamental restructuring of these practices will have to occur.

(b) Suggested Changes

Classic FNCS practices do not describe what exactly the annual fee is for, even if they say it is for the annual physical and a wellness plan. These are, of course, generic terms and ones not easily given to parsing what is being paid for any given services that is part of an annual workup done on a patient. This will have to fundamentally change.

The first thing for these practices to do is have a clear expression of what portion of the annual fee is for the physical and is for the wellness plan. Remember, only one physical is covered (the patient's first Medicare year), but 3P Services are annual. Assume, as an example, that the physician charges the patient $2,000 as an annual fee. The agreement with the patient could provide that of that amount $500 is for the physical and $250 is for the annual personal wellness plan. For the first year the patient is in Medicare, his or her annual fee would be only $1,250, a $750 reduction. $500 of this amount would accommodate the fact that the physician will bill Medicare for the physical and $250 because the physician will bill Medicare for the annual 3P Services. Here is some possible language[8]:

Services for Which Portion of Periodic Fee is Paid.

(a) *Wellness Evaluation*. We agree that of the annual fee of $2,0000, $500 is for an annual physical examination to be provided by the Physician at no additional charge. As a result of the physical, the Physician will develop for You a written health, exercise, and dietary health plan for You to follow ("**Your Individual Plan**").

(b) *Initial Preventive Physical*. The annual physical will not include the one-time "Initial Preventive Physical Examination" available to Medicare patients during their first year of Medicare coverage. This is **a separate examination** and will be billed to Medicare (except for co-pays and deductibles, **for which You will be responsible)**. To accommodate this one-time Medicare coverage (and the services mentioned in the

[8] These numbers are, of course, used only for the sake of example and to describe the concept. They are not intended to be an assessment of worth or value of any service offered to the patient. This language is not offered as legal advice and is not as legally precise as language that would eventually be placed in a patient agreement. Any physician should consult an attorney before inserting any new language in a patient agreement.

following paragraph), Medicare patients will be charged only $1,250 for the year in which they are eligible for the Initial Preventive Physical Examination.

(c) *Personalized Prevention Plan Services.* Your Individual Plan will include the "personalized prevention plan services" (the "**PPPS**") defined in Section 1861(s)(FF) of the Social Security Act (added by the Health Care Reform Act of 2010) as being provided to Medicare patients. The annual fee paid by each Medicare patient shall be reduced by $250 in order to accommodate the Medicare coverage of these PPPS.

III. Fee for Care

FNCS practices were not the only ones to take a hit from the Act. Since almost all physicians running fee-for-care practices have opted out of Medicare, provisions of the Act affecting opted-out physicians will by definition affect these practices.

Section 1395m(a) of the Social Security Act deals with Medicare payments for durable medical equipment. Section 1395m(a)(11)(B) currently reads:

> The Secretary is authorized to require, for specified covered items, that payment may be made under this subsection with respect to the item only if the physician has communicated to the supplier, before delivery of the item, a written order for the item.

This means that for Medicare to pay for DME it must be furnished to the patient pursuant to a prescription from a physician. Section 6405 of the Act changed this provision to read as follows (the new language is underlined):

> The Secretary is authorized to require, for specified covered items, that payment may be made under this subsection with respect to the item only if the <u>physician enrolled under section 1866(j) or an eligible professional under section 1848(k)(3)(B) that is enrolled under section 1866(j)</u> has communicated to the supplier, before delivery of the item, a written order for the item.[9]

Now the physician writing the prescription must be "enrolled" in Medicare, which means that he or she has not opted out.

Section 6405 of the Act goes on to make the same change with respect to home health services, and, if that were not enough, further adds this language to the Social Security Act:

> The Secretary may extend the requirement applied…[above]…[that physicians not be opted out of Medicare]…to all other categories of items or services.

[9] These provisions are applicable to any orders written after July 1, 2010.

Again, this is a moving target, as the Secretary could add all sorts of things to the list, including prescription drugs. That is a huge club to hold over the head of physicians who might entertain the option of opting out of Medicare. If too many or certain items are added to the list, like laboratory services, MRIs and the like, it would effectively preclude adult primary care physicians from opting out of Medicare.[10]

It is likely that the inability of fee-for-care physicians to write prescriptions for DME and home health services, at least those that the patient expects to be paid by Medicare, will badly hurt these practices, and, if the Secretary expands the list into other areas, could effectively put an end to those that have a significant number of Medicare patients.

IV. Conclusion

The provisions of the new Health Care Act discussed above are going to have serious consequences for both kinds of concierge medical practices. Those for FNCS practices can be adequately handled by restructuring patient agreements to modify how annual physicals and wellness plans are dealt with for Medicare patients. Fee-for-Care practices have more of a challenge due to the apparent blanket disallowance of Medicare payments for DME and home health orders by opted-out physicians.

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[10] Physicians have been able to opt out of Medicare only since 1997, after the passage of Section 4507 of the 1997 Balanced Budget Act. See http://www.medscape.com/viewarticle/465262 for a good explanation of the opt out procedure.