

UPDATE ON LEGAL & LEGISLATIVE ISSUES IN CONCIERGE MEDICINE

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I. INTRODUCTION

- (A) Concierge practices are unique and a relatively new method of practicing medicine.
- (B) In 2003-2005 federal regulatory agencies were on alert regarding concierge medicine.
- (C) What has happened recently?
- (D) How does Health Care Reform impact concierge practices?

II. LEGAL BACKGROUND

To truly understand the impact of the 2010 Health Care Reform, we must briefly cover the legal landscape in which concierge practices and fee for service providers operate:

A. Limiting charge rules. A non-participating physician can receive only 115% of the Medicare allowable charge for covered services. (Medicare limiting charge regulations (42 C.F.R. § 414.48)).

- i. If the annual fee charged by a concierge practice covers Medicare covered services, then the additional charge will violate this limiting charge.
- ii. Therefore, annual fees generally cover “extras” such as spa-like waiting rooms, increased frequency of exams, and the physician’s cell phone number.
- iii. Physicians can avoid the limiting charge by opting out.

B. Opt-out rules. Physicians who opt-out of Medicare entirely must follow strict rules:

- i. Physicians who opt out of Medicare can charge a Medicare beneficiary any agreed amount for Medicare covered services as long as the following requirements observed:
 - 1) Physician formally opts out of Medicare program for 2 years;
 - 2) Physician may not receive payment from Medicare for any services provided to any of his or her Medicare patients;
 - 3) Medicare patients may not submit claims to Medicare for medical services, or receive reimbursement from Medicare for such services;
- ii. Physician must enter into written contract with each Medicare beneficiary patient containing certain mandated provisions.
- iii. Physician must file an affidavit with Medicare. 42 C.F.R. § 405 Subpart D.

C. Healthcare fraud and abuse.

i. Participating physicians (and non-participating physicians) are at risk of liability for billing Medicare patients for services that are already covered by Medicare.

- 1) The Office of Inspector General (“OIG”) issued a “Fraud Alert” March 31, 2004 stating: “Charging extra fees for already covered services abuses the trust of Medicare patients by making them pay again for services already paid for by Medicare.”
- 2) Furthermore, the OIG stated: “Non-participating providers may also be subject to penalties and exclusion for overcharging beneficiaries for covered services.”

ii. The Health Insurance Portability and Accountability Act (“HIPAA”) broadly prohibits healthcare fraud. 18 USC § 1035, 1347, 24.

D. State insurance laws.

- i. Similarities between prepayment for health services and health insurance can be drawn.
- ii. The definition of insurance varies on a state-by-state basis.
- iii. Georgia: Several opinions of the Attorney General have considered whether particular arrangements amount to the business of “insurance” thereby requiring an insurance license or HMO certificate of authority. Ga. Op. Atty. Gen. 82-71 (1982)
 - 1) Prepaid dental service plans constitute the offering of insurance if their financial success depends on some participants not fully utilizing the available benefits so as to offset the cost of participants who fully utilize available benefits.
 - 2) Alternatively, if the prepaid dental plan charges each participant the approximate cost of the services rendered to that participant, then no insurance or risk distribution is involved.

State insurance laws (cont.)

- iv. New Jersey and New York have issued warnings against concierge medical practices.
- v. From New Jersey:

“The Department [of Health & Senior Services and the Department of Banking and Insurance] are aware that physicians offering retainer programs assert that the services they offer are complementary to, not duplicative of, the services they are required to render as network providers. In addition, physicians offering retainer programs point out that patients have access to the physician 24 hours per day, 7 days per week. The Departments’ position is that many of the services that providers claim are additional services in fact are required by New Jersey law to be covered under most health benefits plans.”

New Jersey explains:

Most health benefits plans delivered or issued for delivery in New Jersey are required by law to provide coverage for a range of services. The services required to be covered, or for which benefits must be available, include many preventive services, screenings, diagnostic procedures, as well as treatment and services specific to certain conditions and/or illnesses. The requirement for the provision of preventive services is flexible, and permits physicians to alter the schedule and types of services as appropriate to the needs of the patient. In addition, physicians contracting with carriers to be primary care providers are required to have arrangements assuring that those members seeking emergency or urgent care have access to triage services 24 hours per day, seven days per week, and are able to obtain an appointment for urgent care within 24 hours, and more immediate access to care in emergency situations through the most appropriate sources. (See N.J.A.C. 8:38-6.2(d) and N.J.A.C. 8:38A-4.10(b).)

III. HEALTH CARE REFORM IN 2010

The Patient Protection and Affordable Care Act, signed into law by President Obama on March 23, 2010 (P.L. 111-148) and amended by the Health Care and Education Reconciliation Act of 2010 signed into law on March 30, 2010 (P.L. 111-152)

(collectively referred to here as the “2010 Health Care Act”).

A. Increasing Access to Clinical Preventive Services

- i. 2010 Health Care Act provides Medicare coverage with no co-pay or deductible for annual wellness visits and personalized prevention plan services. These services include:
 - 1) Comprehensive health risk assessment; and
 - 2) Personalized prevention plan that includes a 5-10 year screening schedule, list of risk factors and strategy to address them, health advice and referral to education, preventive counseling or community based interventions to address lack of physical activity, smoking and nutrition. (Section 1861 of the Social Security Act, as amended by 2010 Health care Act § 4103).
- ii. Medicare beneficiaries are eligible for the initial preventive physical exam in the first year of Medicare coverage, and for the personalized prevention services thereafter.

A. Increasing Access to Clinical Preventive Services (cont.)

- i. Impact: Increased scrutiny of Medicare payments are a cause for concern for any medical practice billing Medicare or seeing Medicare beneficiaries. Concierge practices are no exception. In particular, concierge practices must be even more careful about ensuring services that are included in the practice's annual fee are not covered Medicare services. Additional criminal penalties make working in a "gray" area more risky.

B. Increased Focus on Eliminating Fraud and Abuse

- i. Sections 6401-6411 of the 2010 Health Care Act make changes to provide for the program integrity of Medicare, Medicaid and Children's Health Insurance Program ("CHIP"), including rules that generally discourage program fraud, waste and abuse.
 - 1) HHS Inspector General is given broad authority to gather information (including information from beneficiaries) to validate claims for payment under Medicare or Medicaid. Section 6402(a).
 - 2) Additional criminal sanctions are added for certain acts of medical fraud and criminal sanctions for medical fraud are made applicable even in the absence of actual knowledge or specific intent. Section 6402(f).
 - 3) Enhanced penalties added for false claims (\$50,000 per violation). Section 6408(a).

- B. Increased focus on fraud and abuse (cont.)**
- (i) Impact: Increased scrutiny of Medicare payments are a cause for concern for any medical practice billing Medicare or seeing Medicare beneficiaries. Concierge practices are no exception. In particular, concierge practices must be even more careful about ensuring services that are included in the practice's annual fee are not covered Medicare services. Additional criminal penalties make working in a "gray" area more risky.**

C. Status of Person Ordering Certain Good or Services

- i. Physicians and eligible professionals must be enrolled with Medicare in order to order or refer patients for durable medical equipment (“DME”) or home health care. (Section 6405 of the 2010 Health Care Act.)
 - 1) Exception exists for physicians that have properly opted out of Medicare. 75 F.R. 24437.
 - 2) If the physician has properly completed the opt-out affidavit, they will already have a record in the Provider Enrollment Chain and Ownership System (“PECOS”) that contains the physician’s NPI and a note that the physician has opted out.
- ii. HHS has the authority to require ordering and referring physicians to have valid PECOS enrollment records for other services too. HHS has yet to designate any additional services.
- iii. Impact: Concierge physicians who are not properly opted out of Medicare and that often order DME or home health care will have to enroll, or stop making such orders or referrals. Concierge physicians should check to ensure that they have properly opted out of Medicare.

D. Individual Insurance Requirement

- i. Imposition of mandate on U.S. citizens and legal residents to have qualifying health coverage (Section 1501 of 2010 Health Care Act).
- ii. Impact: Influx of insured patients to primary care practices may cause traditional practices to become crowded. More physicians and patients may seek the concierge model for better access and improved physician-patient relationships.

IV. STATE INSURANCE REFORMS

- A. Maryland Insurance Administration Report on “Retainer” or “Boutique” or “Concierge” Medical Practices and the Business of Insurance (Jan. 1, 2009) – warns about the following indicators that a concierge practice constitutes insurance:
- i. Annual retainer fee covers unlimited office visits or a limited number of services that the physician cannot reasonably provide to each patient in his or her panel.
 - ii. No limitations on the number of patients accepted into the practice.
 - iii. Annual retainer fee does not represent the fair market value of the promised services.
 - iv. The physician has substantial financial risk for the cost of services rendered by other providers.
 - v. The retainer agreement is not terminable during the contract year and/or does not provide for pro-rated refunds.

V. CONCLUSIONS

- A. Healthcare reform's focus on primary care and preventive care significantly impacts the services that a concierge practice can include its annual fee.
- B. Healthcare reform's focus on eliminating fraud, waste, and abuse, make it even more important for concierge medical practices to ensure that they are compliant with Medicare billing rules or Medicare's opt out rules.
- C. Concierge practice may gain popularity among physicians and patients as the individual insurance mandate becomes effective.

Thank you!

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