During the past several years, an increasing number of health care providers have been redesigning the financial and contractual relationships between themselves and third party payors and their patients to engage in one form or another of what is variously known as “concierge,” “boutique,” “retainer” or “VIP” medicine, a development that may have significant implications for the legal relationship between health plans and their enrollees and contracted and non-contracted providers. This trend has been driven partly in response to downward pressure on health plan provider reimbursement and physician frustration with real or perceived increases in health plan contractual and administrative burdens that may be seen as detracting or interfering with the physician patient relationship, and partly in response to demands from patients, particularly the chronically ill, for a more responsive and personalized treatment relationship with their physicians.

The economic and lifestyle issues for physicians can be compelling – a physician may be able to maintain the same income by covering several hundred patients that they formerly made while covering thousands, with significantly fewer administrative obligations and virtually no bad debt. Concierge practices can currently be found operating in some form in about half of the States. There is an association for such
practices that has recently changed its name from the “American Society of Concierge Physicians” to the “Society for Innovative Medical Practice Design” (www.conciergephysicians.com).

Some critics of these arrangements contend that the physicians are taking advantage of vulnerable patients who fear abandonment or feel compelled to pay the retainers in order to continue receiving necessary medical care. Others argue that they are catering to the “healthy wealthy,” pulling local physician capacity offline and increasing the burden on the remaining providers in the area and providing a level of dedicated care management to a relatively few well off patients that should be available to everyone who needs it.

There are a variety of models of concierge medicine currently in operation, and they may offer a wide range of value added benefits to their patients. In exchange for an annual or monthly membership fee, the physician generally agrees to limit the number of patients they accept in their practice and to offer more personalized services to their members, including annual physicals or wellness exams, same or next day appointments, telephone physician advice, including review of labs and tests, preventive services and counseling, house calls, guaranteed response time on patient call backs, referral and prescription requests, access by email, completion of medical history and referral forms, scheduling with referral providers, publication of a patient newsletter, availability during non-business hours, etc.
The most prevalent model involves the payment of an annual fee (ranging from $1500 to $4000 per year for an individual) and an agreement by the patient to make immediate payment for services based on a fee schedule developed and maintained by the practice. The physician agrees not to bill the patient’s insurance, although the patient may be expected to maintain any coverage that they do have in order to cover hospitalization and specialty and catastrophic care. In the second model, the patient may pay a lower fee and the physician does continue to bill insurance at contracted or out of plan rates, and the fee charged is only for the value added services not otherwise covered by the third party payor. The third model is similar to traditional fee for service practice, where the physician bills the patient for all services rendered and the patient submits claims to their health plan with the knowledge that some services rendered may not be covered by their plan.

The American Medical Association has issued guidance supporting the development of concierge medical practice as consistent with the AMA’s traditional support of pluralism in the delivery and financing of health care and establishment of trust-based physician patient relationships. See American Medical Association, Policy H-140.893. The AMA does caution its members, however, to: be careful not to apply undue pressure on patients to enter into such an arrangement, particularly vulnerable patients who may fear abandonment; be mindful of any implications the arrangement has for the patient’s insurance coverage; exercise care in transitioning patients to other providers and to clearly articulate the difference between special services and amenities and reimbursable medical services. See AMA Code of Ethics E-8.055. The AMA has also
reinforced its traditional positions that physicians should refrain from providing unnecessary care just because there is a patient demand for the service and they should strive to provide some level of care to patients regardless of the individual’s ability to pay.

**Legal Issues for the Provider**

**Contracts.** A physician making the transition to concierge practice will typically terminate his or her contracts with all commercial third party payors in an effort to avoid the restrictions of contracted reimbursement, submission to utilization review and application of the patient hold harmless clause. The physician will also typically enter into some form of Patient Agreement, whereby the patient agrees to pay the annual fee in advance and all fee schedule charges at the time of service in exchange for access to a specific menu of enhanced services. The patient may also acknowledge that the physician does not participate in any third party payment plan and either agrees not to submit any claims to their plan or to accept whatever level of reimbursement their plan may provide. The agreement may state whether the physician is refusing to process or submit any claims to third party payors, which may be necessary to maintain private contracting status with Medicare or for commercial populations in some jurisdictions, or whether they are specifically offering to perform that service for patients as part of the annual fee. A physician may also be legally obligated to reimburse the health plan for any amounts that are inadvertently being billed to the plan by either the patient or the physician’s office. See *Opinions of the Maryland Attorney General 00-030, 03-005.*
Insurance Licensure. Some state laws, such as the California Knox Keene Health Care Service Plan Act, may prohibit arrangements whereby physicians undertake to arrange for the provision of health care services on a prepaid or periodic charge unless the provider has an HMO license or other form of state licensure or certification allowing the provider to assume risk. The Office of the Insurance Commissioner of Washington issued Draft Advisories challenging the receipt of a retainer as the acceptance of risk without appropriate licensure and as constituting illegal “access fees” for the receipt of covered insurance benefits.

As a result, some concierge arrangements are structured so that the retainer is characterized as a flat fee for specific services, or the arrangement is billed in arrears to avoid the application of state laws prohibiting prepayment in the absence of appropriate licensure. Legal practitioners representing concierge practices will need to help structure the arrangement in a manner that avoids characterization as an unlicensed insurance arrangement. This may not be a problem in jurisdictions that make the regulatory distinction between “insurance risk” (assumption of risk for both services rendered by the provider and for certain specified referral services) and “service risk” (assumption of risk only for services directly rendered by the practitioner). This same distinction prevents physicians accepting capitated arrangements for personally performed primary care and other professional services from being characterized as impermissible insurance arrangements in some jurisdictions.
Hold Harmless/Balance Billing Enforcement. An additional insurance regulatory issue at the state level is the application of the patient “hold harmless” clause, which generally prohibits balance billing patients for the costs of non-covered services. See generally, Maryland Opinion of the Attorney General 98-018. Providers with third party payor participation agreements may be prohibited from billing the patient for any amounts not reimbursed by the plan, unless the services are contractually excluded (e.g., cosmetic and experimental procedures, etc.). The Maryland statutory hold harmless even applies to non-contracted providers, Maryland Health General Code § 19-710(i), so the hold harmless is still an issue even where a physician has terminated all payor participation arrangements. However, the Maryland Attorney General has opined on several occasions that physicians and patients may enter into “private contracts” outside an HMO coverage arrangement, provided that the HMO does not authorize the service, refer the patient to the practitioner or receive any claim for payment. Opinions of the Maryland Attorney General 00-030, 03-005. The Attorneys General of Texas and Arkansas have also issued opinions on balance billing issues.

In light of the facts that violation of the ban on balance billing is a fairly frequent complaint among MCO members, and that enforcement of the hold harmless clause is one of the relatively few areas where state insurance regulators may have direct statutory jurisdiction over licensed health care professionals, physicians should make significant efforts to understand the application of the hold harmless rules in their jurisdiction and to work with their patients to avoid violations and enforcement actions.
Accessing Patient Third Party Coverage. Even if a physician terminates all formal contractual relationships with third party payors, they may continue to have unavoidable interaction with the health plans providing other benefits to their patients. Physicians may agree to perform the billing function and assist their patients in submitting claims to the carrier. They may be billing the plan themselves as an out-of-network provider or under the applicable terms of a non-Preferred Provider or Point of Service arrangement. Patients may still need physician orders for covered ancillary services (lab, imaging, pharmacy, DME, home care, etc.), referrals to specialists, hospital admissions and physician orders to other covered services requiring physician authorization. Providers need to understand the terms of their individual patient’s coverage and be willing to work with them to maximize their access to covered benefits and avoid unnecessary coverage denials and balance billing issues.

Medicare. Section 1802 of the Social Security Act already gives physicians and fee for service Medicare beneficiaries the option of “private contracting” outside of the Medicare program for the receipt of services at privately negotiated rates not subject to the Medicare limiting charges. Once the physician “opts-out” of Medicare participation by submitting an appropriate affidavit to the Medicare carrier, the patient agrees to accept full financial responsibility for the cost of the services rendered and not to submit a claim to Medicare for the privately contracted services. The physician agrees not to bill Medicare or accept capitation from a Medicare Advantage organization for any service (except for certain emergency or urgent care services) for any Medicare patient for two years from the date the affidavit is signed. See generally 42 C.F.R. §405.400 et seq.
However, there are a number of federal issues for physicians who desire to bill Medicare for some of their patients or for some portion of the services provided pursuant to a retainer arrangement. Like some state insurance regulators, the federal Centers for Medicare and Medicaid Services (CMS) has expressed a concern that the annual retainer may be considered an insurance policy, since it may cover services that Medicare does not -- such as an annual physical -- and thus violate the Medicare supplemental insurance provisions of the Medicare statute, which establishes minimum standards for Medigap policies and requires them to comply with all applicable state laws regulating such policies.

A second area of concern for CMS is that the additional fee paid by the patient may violate the Medicare limiting charge and assignment rules if the retainer agreement includes covered services billed to the Medicare program. The limiting charge rules prohibit a physician from charging a Medicare beneficiary more than a fixed percentage over the Medicare physician fee schedule for covered services. Under the assignment rules, Medicare participating physicians agree to accept the Medicare fee schedule rate as payment in full for covered services. Thus, if the retainer agreement includes features that enhance or waive applicable copayments for covered services, the agreement may violate either the limiting charge or assignment rules. There may also be a False Claims Act (31 U.S.C §§ 3729-3733) issue if physicians fail to include the cost of the annual fee when billing Medicare – the physician may be seen as illegally misstating the true amount charged to Medicare beneficiaries.
Based on the legal concerns and anecdotal complaints that Medicare beneficiaries who did not pay the retainer fees were being dropped by their physicians, a variety of measures have been introduced at the federal level containing provisions that would essentially criminalize any practice design that charges a monthly fee to Medicare beneficiaries. These statutes would provide for sanctions and exclusions for physicians charging an “extraneous or incidental” fee to a Medicare beneficiary or requiring a patient to purchase an item or services as a pre-requisite to receiving other covered services. Thus far, there has not been significant legislative traction for these measures, due in part to a low number of Congressional sponsors and the existence of larger Medicare-related issues on the legislative agenda.

**Legal Issues for the Patient.**

The legal issues facing the patient will primarily center around the execution of a Patient Agreement with their physician and the interface with any third party payor coverage that they would otherwise have access to. There may also be issues of common law abandonment if a physician terminates a treatment relationship with a patient who declines to enter into the Patient Agreement if they are undergoing a course of treatment and the physician has not made clinically appropriate arrangements for transfer of the patient’s care to another qualified provider.
Patient Agreements. Is any portion of the retainer refundable if the patient terminates after a partial year or otherwise leaves the practice prior to receiving some of the specified services (e.g., annual physical)? Is the patient being improperly induced to accept the agreement through promises of higher quality care and/or perceived threats of abandonment? Has the impact on the patient’s otherwise available insurance coverage been fully disclosed and documented? If a patient has contractually agreed to refrain from billing their health plan to avoid triggering a hold harmless provision, how does the agreement cover situations where claims may have been intentionally or negligently submitted to the carrier? Are there unreasonable penalties for opting out of the arrangement at some point during the contract year?

Legal Issues for Health Plans

Health Plans may have to recognize that a certain percentage of their enrollees will inevitably opt to participate in concierge medicine practices and that some of their contracted physicians may terminate their existing arrangements with the Plan to participate in such practices. Depending on the number, locations and specialties of the physicians involved, the Plan may have to adjust its network configuration to compensate. Although there is a general bias on the part of Health Plans for enrollees to receive services from within the contracted provider network, there may also be cost savings if a significant number of relatively high utilizing patients opt to receive services under arrangements where they pay out of pocket and agree to refrain from billing the plan for the services.
In addition, Plans should consider developing internal policies and procedures for handling claims from physicians or patients in concierge practices and hold harmless/balance billing enforcement. Adequate arrangements should also be made for an orderly and appropriate transition of patients whose physicians terminate their agreements with the plan to the care of another contracted provider in situations where a patient declines to join the physician’s concierge practice and elects to continue receiving physician services through the plan’s contracted network.

Conclusion

Concierge medicine is a growing phenomenon and it remains to be seen whether it is a short term reaction to market and other forces, or whether it will play a significant part in the future delivery of professional medical services. There are a variety of significant legal issues that will need to be worked out at the state and federal levels and additional regulation may be in the offing as regulators continue to examine these arrangements more closely. Legal practitioners will need to assist physician and health plan clients in working their way through the fairly detailed administrative issues that need to be addressed.

1 A hold harmless clause generally becomes effective in one of two ways: (1) it can be included as a specific term of the services agreement between a health plan and a participating provider, or (2) it can be mandated by statute or regulation, regardless of the existence of any agreement between the plan and the provider. Under the Maryland scheme, the hold harmless is a statutory consumer protection that applies to the patient’s interaction with any provider, regardless of whether the provider has a contract with the payor.