

Regulating the Conduct of Physicians in a Health Insurance System:

Some Lessons from American and European Experience

**Questions addressed to
Professor Rich Feeley and Dr. Jan Bultman
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Health, Nutrition and Population (HNP)
Human Development Sector Unit
Europe and Central Asia Region



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Note to the Reader

This small note was an outgrowth of discussions within the Russian Government related to Health Reform and Physician Regulation. Work Groups were actively discussing issues and debating options for legislative proposal. Some questions were asked of Bank experts and consultants regarding the international experience. There was not enough time in this debate to have experts travel from other countries and meet directly. Instead, a somewhat informal phone meeting was set up between Europe, United States and Moscow. Questions were asked and responses were given over a period of just a few hours. Four topic areas were covered:

- Limiting Financial Abuses by Providers
- How Are Insurance Regulations Enforced?
- Physician Self-Regulation
- Clinical Protocols

Following the phone conversation, a request was made to write up the notes and make it available in Russian and English. This note reflects this rather impromptu discussion, but one which might be a timely reference as Russia deliberates on choices related to health reform.

Limiting Financial Abuses by Providers

Q. How do these insurance systems prevent doctors from charging for covered services or charging patients unauthorized amounts in addition to the insurance payment? Is this a problem in Europe and America?

A. In general, this is not a problem. Insurance contracts clearly delineate those areas in which a physician can charge in addition to the insurance payment (co payments, uncovered services) and specify if the physician can collect an amount from the patient in addition to the insurance payment. Continuation of the insurance contract is clearly conditioned on compliance with these rules. Patients will complain if they believe that the doctor is charging inappropriately. Physician income is mostly earned from the larger insurance programs or sickness funds, and the physician cannot afford to lose “provider status” which permits him to obtain reimbursement from these funds. As a result, there is little unauthorized charging, although (in the U.S.) physicians sometimes lobby to be allowed to charge in addition to insurance fees they consider inadequate. A few physicians may drop out of an insurance plan if they consider fees too low and they have a high income clientele, but there is little unauthorized charging.

In addition to the penalties imposed for illegal charges to the patient, there are two other factors that explain the high level of compliance. Physicians are well paid (3-5 times the average wage in the U.S., 2-3 times the average wage in Europe). In addition, patients are fairly well-educated about the rules governing their insurance plan, and will call the insurer to complain if they feel they are being charged for a covered service. The insured can also send a formal complaint to their insurer or sickness fund. A hotline can also be very helpful. In Bulgaria, complaints of insured, via a new hotline, about extra charging by contracted GP's led to cancellation of a few contracts which helped prevent extra charging by other GPs.

Q. Do doctors take payments for arranging referrals or jumping a queue for specialist care? How is this controlled?

A. This is not a major problem in either the U.S. or Europe. In the U.S., waiting times for specialist visits, hospitalization and procedures are short because of the high capacity associated with high levels of health spending. Waiting lists are controlled by the hospitals/specialists, not by the referring gatekeepers. If doctors did attempt to obtain payment for referrals in the U.S and in the EU., this would likely be interpreted as a prohibited payment under the relevant insurance contract.

In The Netherlands, charging any tariff that is not authorized by the national health tariffs authority, is forbidden, and a violation and can be prosecuted by the Economic Control Services, leading to fines. It can also lead to cancellation of contract. Insurers take a more active approach to waiting lists for elective surgery in The Netherlands by publishing waiting lists and waiting times of hospitals on their websites. Many of them offer mediation to their insured to get them treated as soon as possible. Sometimes treatment also is offered abroad (incidentally or based on a contract with a foreign health services provider).

Q. Do referring doctors take payment from the doctors/facilities that receive the referrals? How is this prevented?

- A. This practice, usually known as fee splitting, is specifically banned under the American social insurance programs (Medicare and Medicaid) and could be interpreted as “insurance fraud” under state laws governing private insurance programs. It would clearly result in termination of the insurance provider contract, and could result in criminal fraud charges.

This problem is in general unheard of in The Netherlands; the problem has been more the other way round, i.e., that doctors do not refer when they should do so for medical reasons, but do not refer in order not to save the payment by the patient (or the reimbursement by the sickness fund). Patient pressure and regular quality control procedures help in preventing such practices and can lead to redress in case something has gone wrong because of late referral.

On the other hand, there has long been a kind of conflict of interest between midwives and obstetricians about the assistance in normal deliveries and what to do in case of potential obstetric risks. This is not physician-to-physician referral but still illustrative. Midwives have the mandate in The Netherlands to independently offer prenatal care and assist in normal deliveries at the house of the patient or at the polyclinic (the latter are all adjacent to hospitals). However in case of potential obstetric risk the midwife must send the patient to an obstetrician. If this happened, than the obstetrician could decide, unilaterally, to keep the patient under his/her surveillance and to take the full reimbursement. This has caused problems: midwives referring too late, or complaining about the loss of income when they did perform services. The problem has been solved in two ways: a split in the honorarium and the creation of an obstetric indications list. The fee split provides the midwife with payments for the three periods: prenatal, durante partu and post natal, dependent upon who actually does the work. The midwife may refer the patient for a single consult to the obstetrician (who will be reimbursed for this), and based on his/her advice, the midwife can continue herself or may refer the patient for the remainder of the pregnancy to the obstetrician. After the delivery, assisted by the obstetrician, the midwife can do the post natal care at home, in case the patient is discharged the same day. The Obstetric indications list, is very precise and divides pregnancies in low, medium

and high risk. Low risks can be handled safely by midwives (and by GP's in rural areas without a midwife). For medium risks, the obstetrician will be asked to evaluate the patient and he/she may advise for a hospital/polyclinic delivery. Even in these cases the midwife may assist the patient, but only in the hospital setting and with the obstetrician around the corner. All high risk pregnancies are taken care of by obstetricians. All hospitals have concluded contracts with the (self-employed) midwives to allow them to do independent assistance of deliveries in their polyclinics.

Q. Can physicians profit from ownership of facilities to which they refer patients?

- A. This is prohibited in the U.S. Medicare and Medicaid (social insurance) programs which control about half the insurance market, and would result in the loss of provider status and possibly a criminal fine. For example, it would be illegal for a primary care physician to hold an interest in a diagnostic X-ray facility to which he refers patients. However, it is not illegal for the doctor to buy the radiology equipment and hire a radiologist for his own clinic, or to go into a group practice with a radiologist. This is currently leading to excessive dispersion of CAT scanners and even MRI machines in clinics.

In Europe, this would be more limited because such machines are usually only purchased for non-profit hospitals and the number and location of such machines would be subject to planning controls. In The Netherlands, physicians cannot profit from ownership. The licensing system for facilities prevents this. It further prevents physicians from installing high-end equipment in private offices (need to follow a certificate of need procedure for expensive and complicated equipment and medical procedures).

Q. Are there limits in the U.S. and Europe on incentives which drug companies can offer to physicians to prescribe particular medicines?

- A. This is an area of great concern. Receiving a direct payment in the U.S. to prescribe a particular medicine would be a violation of the physician's ethical responsibility to the patient, and may violate specific insurance rules. However, "gifts" from pharmaceutical companies to prescribing physicians (including free samples, luxurious "educational" seminars, etc.) have been difficult to control. Some drug companies will also pay doctors for "research" which involves the collection of data on patients in their practice who are taking the medication in question. This type (post-marketing) research is not meant to solve any reasonable research question but is just meant to get the doctor accustomed to prescribing the new drug.

In The Netherlands, this type of research is seen as unethical and the Dutch Association of GP's has established a procedure to review proposals for drugs research and advises members on participation. In addition, any hospital, engaged in research also has its research committee, which will review the research proposals, including the ethical aspects. *Dutch law prohibits physicians to accept gifts etc from the drug industry, but post-graduate education can pose a grey zone. Some drugs manufacturers have been brought to Court by the State Health Inspectorate, which has the formal role of enforcing the marketing rules.* The accreditation of (mandatory) post-graduate training courses also has diminished the dominance of the pharmaceutical industry over these courses. (Note: direct advertising of prescription medicines also is forbidden in The Netherlands). Another issue is the possibility to get kickbacks from the medical implants industry as many orthopedic and cardiac surgeons can exercise influence on what type of prostheses/endorthesis is going to be used. There have been some very visible court cases in Germany in which orthopedic and cardiac surgeons were getting kickbacks from the industry (posted on their Swiss Bank accounts). Cost/effectiveness analysis (HTA) of prostheses and implants has been proven to be very helpful in supporting decision making about reimbursement or buying these supplies.

How Are Insurance Regulations Enforced?

Q. How are abuses of payment rules (illegal charges to patients, kickbacks, etc.) identified and punished?

- A. There are at least three avenues to identify abuses in the U.S.:
- complaints filed with the insurance company or employer (the purchaser of the policy in the U.S.) by the aggrieved patient;
 - review of claims by the insurer or claims processing company (in the case of the American social insurance programs); and,
 - investigations by special "fraud control" task force for the U.S. social insurance programs. Such groups include on-staff doctors and nurses, lawyers, and accountants. They are located in the Government agencies which oversee the program, and may even carry out investigations where "mystery patients" seek care from a suspect doctor;

In The Netherlands, this is more or less the same for insured and sickness funds/insurers. Financial oversight and supervision of the fraud preventing/combating performance of insurers is done by the public Health Insurance Supervision Authority (College Toezicht Zorgverzekeringen). Besides this, the Economic Control Agency (Economische Control Dienst, ECD) supervises the implementation of the tariffs set by the National Health Tariff Authority (College Tarieven Gezondheidszorg). The State Health Inspectorate can also bring cases to the ECD.

Available sanctions include a broad range of options, including:

- refusal to renew an insurance provider contract when it expires;
- recovery of illegal payments (or banned payments made by a patient);
- termination of an existing provider contract;
- administrative fines;
- criminal fines or, in egregious cases, jail terms for the provider;
- referral to the state licensing authority (which could take the provider's license to practice medicine or operate a facility).

In the American social insurance programs (Medicare and Medicaid) these sanctions (short of criminal penalties) can be imposed through an administrative process, with evidentiary hearings held by administrative hearings officers. Such cases do not go into the regular court system unless the provider appeals.

Q. Is there something in the way in which American/European health systems are organized which makes insurance rules a more effective control mechanism?

- A. Yes. Most primary care physicians and many specialists are independent contractors who are dependent on insurance payments for their livelihood. They cannot afford to lose an insurance contract -- effectively, they have lost their job. Even where physicians are employed by a hospital, the hospital is dependent on payments by insurance companies or sickness funds, and will discharge the physician or force changes in his conduct rather than losing the insurance payments. "Autonomization" of Russian clinics and hospitals would likely improve the responsiveness to insurance regulations if the bulk of the provider's funding comes through the insurance mechanism. Likewise for formalizing informal payments and including them in the package of benefits description.

Q. Can American or European insurers/sickness funds require changes in hospital management?

- A. Although the insurers do not have this direct control, the dependence of hospitals and clinics on insurance funding means that such facilities are ultimately responsive to demands for changes in management practice. Certain hospital chains in America were identified by the Medicare program to be engaging in fraudulent financial practices, and the financial managers responsible were discharged by the responsible corporate board.

In The Netherlands, insurers also have no direct control over hospital boards. The same is true for the government, as regards the non-public facilities. But they all can exercise pressure and do occasionally. In France, where almost all hospitals are public, this of course in the domain of the authorities.

Q. Who employs the physicians who review the conduct of providers in a health insurance system?

- A. In the U.S., the insurance company, or the contract administrator for the social insurance program, employs the physicians (often on part time contracts) that grant prior approvals for restricted procedures. Physicians involved in investigation of fraud and abuse by providers are also employed directly or on contract. Most insurers or administrators will employ physician to review anomalous cases identified by physician claims profiling or patient complaints. However, there is a history of the social insurance organizations using groups of physicians (“Professional Review Organizations”) affiliated with medical societies for some reviews of the necessity and appropriateness of care. In the U.S., insurance policies and provider contracts contain clauses specifying that only “medically necessary” care will be reimbursed, and most specify that the provider cannot recover from the patient for procedures or services found not to be “medically necessary” by the insurer during a claims review.

In Germany, regular review of medical practice (claims review) is done by the so-called Unions of Panel Doctors (Kassenaerztliche Vereine) which represent all contracted physicians. These Unions have special departments for claims review, which they perform for all sickness funds under an arrangement overseen by the Government regulator. A negative finding by this review panel can result in the denial of payment for unnecessary or inappropriate services. These Unions have an interest in doing this to ensure that every doctor gets his fair share from the limited budget (under the points system).

The Dutch insurers employ their own physicians for claims (and to some extent) quality review. There have been, in the past, in some regions, independent regional entities outside the sickness funds that employed doctors for claims review. But they have disappeared with the introduction of competition between sickness funds and with the onset of risk bearing for the sickness funds.

Physician Self-Regulation

Q. What role do physician societies play in controlling physician behavior?

- A. Physician societies are voluntary organizations in the U.S. -- doctors are not required to belong. However, these organizations do promulgate codes of ethical conduct for their members, and membership can be revoked for violation of the code. The code specifies the physician’s professional obligations to his patient. Because membership in the physician organization is voluntary, loss of membership for ethical violations does not automatically result in the termination of the license to practice medicine (granted by the State {oblast}), nor does it automatically result in loss of insurance provider status. However, a disciplinary

hearing and loss of membership for ethical violations are likely to adversely effect referrals and may result in investigation by the insurer or licensing body.

Invoking the ethical code of a physician organization is perhaps most useful when an action is unethical, but not per se illegal or prohibited by insurance regulations, and is also embarrassing to the profession. Consensual sex between psychiatrist and patient in the U.S. is an example of such a transgression of the ethical code, and well publicized cases were followed by disciplinary hearings by the American Psychiatric Association.

It is more or less the same in the EU. (In Germany, membership of the Doctors Chamber is mandatory for practicing physicians). In The Netherlands, the former professional (rather secretive) courts for doctors, instituted by the doctors association, have been abolished due to the adoption of stricter patients laws. All complaints about the performance of medical staff go to regular courts, which have special chambers to address medical (and other health professional) cases, chaired by a professional judge (lawyer) and with independent medical advisors. (see attachment: NL law on individual health care professions act). Although the Dutch Medical Association still issues its ethical code and guidelines for doctors, the role of this association is lessened as a consequence of several new patients rights protection laws on:

- clinical research;
- complaints (instructing every health institution to establish a complaints procedure and committee);
- the model contract between doctor and patient; and,
- the ombudsman in psychiatric institutions).

Q America relies on “self-regulation” by physicians? How does this work?

- A. There are two areas in which physician self-regulation in the U.S. has generally been regarded as successful:
- 1) granting of specialist qualifications; and,
 - 2) accreditation of training programs

For each medical specialty, there is an independent body (usually called a Board), loosely affiliated with the specialty medical society, which sets the national examination for the specialty qualification (and, more recently, re-qualification). If the physician does not maintain this specialty qualification, s/he will be unable to obtain the higher rates payable to specialists by insurance companies, nor will s/he be able to obtain professional liability insurance in the specialty. S/he will also be unable to obtain privileges to practice the specialty at a hospital. As a result, almost all American physicians obtain a specialty qualification (internal medicine, family practice and pediatrics are all specialties). The independence of the specialty board permits it to respond quickly to changes in medical knowledge and require up-to-date skills of applicants. The Boards have proven reasonable

gatekeepers to the specialties, since they have motivation to discourage unskilled competition within the specialty.

Both medical schools and residency programs are accredited by groups composed of existing schools/programs. These groups have an incentive to maintain reasonably high standards in order to deter competitors that cut quality to cut price. In effect, these accreditation programs become a pre-requisite for state (oblast) licensure of a physician, since the candidate physician must graduate from an accredited medical school (or take a strict equivalency examination for foreign medical graduates), and must successfully complete an accredited residency program.

It is the same for The Netherlands, albeit that registration/licensing of specialists is now embedded in the new Act of individual health professions.

Q. How is a physician disciplined for unethical conduct? What roles do the State (oblast) Government and Central Government and physician society play?

- A. In the U.S., physicians are licensed by each State (oblast). A license is granted based upon completion of approved training programs and a qualifying national exam. "Good moral character" is required, and the license can be denied or revoked after conviction of serious crimes. Membership in a physician association is not required for licensure. Licenses require periodic renewal and the physician must demonstrate completion of a set number of hours of continuing medical education prior to each renewal. The license may be revoked, restricted, or renewal may be denied for a variety of reasons including:
- criminal convictions;
 - drug or alcohol abuse;
 - a proven pattern of professional negligence or incompetence.
- State licensing boards employ investigators and hold their own evidentiary hearings. However, less than 1% of licensed physician will have their license revoked or limited during a professional career, and any license action based on insurance fraud will usually occur only after the insurer has acted.

In The Netherlands, the Central State Health Inspectorate can also revoke a license., via a court decision.

Q. So what is most important in the U.S. as a limit on inappropriate physician conduct -- self-regulation, state licensure, insurance contracts?

- A. All are important, although the insurance relationship is now the most important. State licensing is a pre-requisite to participation in the medical care system, and is linked to self regulation of training programs and specialty qualifications.

However, in the area of financial abuse, and to some extent, inappropriate medical care, insurers will usually act before the state licensing body takes action. In the area of professional ethics, the medical societies have more fully developed codes of conduct (compared to state licensing bodies), but are slow to act against a particular member physician. However, the threat that the State licensure agency will act and embarrass the physician association for tolerating unethical conduct stimulates some ethical enforcement actions by the physician association. Because physician association membership is voluntary, state licensing is ultimately a more effective weapon against truly incompetent or unethical physicians.

As mentioned before, in The Netherlands, there has been a move away from self regulation towards more government regulation.

Clinical Protocols

Q: What role do clinical protocols play in the practice of medicine and in the insurance system?

A: In general, insurance programs in the United States and Europe do, in general, not specifically adopt clinical protocols as the basis for reimbursement, or require that a protocol be followed as a condition for reimbursement. However, protocols may be used in a number of ways:

1. As evidence of what is medically necessary and appropriate when a provider's practice is identified as an "outlier" compared to the normal pattern of practice. In effect, if the insurer claims that the care is unnecessary or inappropriate, the protocol will be used as evidence of what is appropriate. The physician may rebut the presumption that his care is inappropriate by giving evidence that the clinical situation varied from that assumed in the protocol;
2. In The Netherlands, clinical guidelines are used as a reference point in the description of some drugs (like growth hormone), as part of the benefits package, only to be prescribed in accordance with a protocol endorsed by the professional association or the Health Council (Scientific advisory Body);
3. As the basis for continuing medical education programs;
4. As a "checklist" in evaluating the quality of care given by a provider;
5. In professional negligence disputes. The plaintiff (injured patient) may use the protocol as evidence that the doctor's care deviated from normal medical practice. The doctor may defend himself against a negligence charge by giving evidence that he complied with the protocol.

In Germany these distinguish between Richtlinien (mandatory) and Leitlinien (advisory type of guidelines), but the number of mandatory guidelines are limited and more or less formulate the "state of the art": e.g., "in case of such and so diagnosis, than the doctor should..."

Q: How are clinical protocols developed?

A: In the U.S., and in most of Europe these protocols are usually developed by medical associations (physician societies) or their affiliates. This is usually a process in which the literature is reviewed for evidence on efficiency and effectiveness, the evidence is being evaluated and rated/ranked (randomized clinical trial with a statistically sound number of patients involved, being the gold standard, quasi-experimental studies with control groups being held as a silver standard, and so on), protocols are then developed which relate these findings to everyday practice, feedback is sought from the profession in general (consensus development), and finally agreed. Guidelines and protocols are then issued to the members of the society, and made available to insurers. However, adherence to the protocol is not a specific requirement of an insurance program.

Protocols are also developed within closed systems of medical care, such as Health Maintenance Organizations. The same process is followed, and the expectation that a physician within the organization must follow the protocol is usually much clearer. The development of clinical practice guidelines is also furthered by public bodies like ANAES in France (which has the mandate to perform health technology assessments), SBU in Sweden, the Institute of Clinical Excellence (NICE) in the UK, and the Dutch Health Insurance College (which issues a Compass on Pharmaceuticals as well as a Compass on Diagnostics, prepared in close cooperation with representatives of the professions).

During the Moscow March 2004 Seminar on quality of care, technology assessment and clinical guidelines, Professor Bashinsky presented a good overview of “how to develop” protocols, referring to accepted international best practice (AGREE framework). This presentation is available on the World Bank Website.