Virtually 100% of the German population has health insurance. Of this 100%, ~90% are members of the Statutory Health Insurance plan. This insurance plan assumes responsibility for practically all of the costs of treatment; self-participation by the patient in the costs is minimal. To counteract the financial deficits of the Statutory Health Insurance funds, the Health Care Reform Act was introduced in 1993, bringing with it massive economy measures for everyone involved in the health sector. For the practitioner sector, this new legislation provides for, among other things, revision of the structure and the reimbursement of laboratories. In this context, the originally agreed-upon introduction of lump-sum payments as reimbursement for laboratory tests was abandoned, in the face of vigorous resistance by the medical profession. Instead, the system of reimbursement for each individual test continues to apply. However, the number of tests is to be limited for each specific group of doctors. In addition, the laboratory fee in the practitioner sector is being reduced by 20%.

**The German Health Insurance System**

Present-day Germany has ~80 million residents, 99.8% of whom have health insurance, either private or SHI.

**The Statutory Health Insurance System.** About 90% of the population belongs to the SHI plan (2). The health insurance funds are financed by contributions from their members. For 1993, the average contribution by the insured person was 13.4% of his or her gross income (3). Both employee and employer provide half of this sum. For employees in western Germany, insurance is obligatory up to a monthly income of US$ 3253 in 1993 (4).

SHI is characterized by the principles of self-administration, third-party payment, and solidarity. The self-administration principle means that health insurances are financially and organizationally independent. Although they are under the supervision of the state, they are not subject to state management. Third-party payment means that, in case of illness, the insured persons receive all the required medical attention without having to pay for them directly. Instead, the physician is reimbursed from the health insurance fund via the regional association of physicans. Only in a few exceptions does the patient have to finance the costs in advance. Consequently, self-participation in costs by the patients has been very low. Even with the new Health Care Reform Act, patients' payments are still low in comparison with those in other countries. The solidarity principle means that contributions from insured persons are based on their income regardless of age, sex, health-risk, etc. (2). Family members are also covered by the insurance at no additional cost.

**Private health insurance funds.** About 10% of the population has private health insurance (2). Every person who is not legally obligated to join an SHI plan can obtain private health insurance.

Generally speaking, people who choose the private insurance program are self-employed, civil servants, and employees with incomes above the obligatory insurance limit of US$ 3253 per month. The insurance contribution of these individuals depends on the benefits offered, the person's age, special risks, etc. Each member of the family must be insured individually.

The insured persons must first pay the medical bills themselves. Depending on the insurance policy, all or part of the costs incurred are then reimbursed by the health insurance.

**The SHI Reimbursement System**

**Ambulatory sector.** About 95% of all practitioners have received the "Kassenzulassung," which means

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1. Boehringer Mannheim GmbH, Department of Communication and Health Policy, Sandhofer Str. 116, 68305 Mannheim, Germany. Fax Int + 49-621-759-2902.

2. In addition to the presentation at the Clinical Chemistry Forum on November 1, 1993, this paper incorporates discussion of the rapidly unfolding developments in healthcare policy regarding the laboratory sector in Germany through the end of January 1994.

3. In 1990, East Germany, which had been under Communist rule, was reunited with West Germany. Because figures and data from the Communist period and the transition phase are not directly comparable with the present situation, I shall mostly restrict myself to figures relating to the western part of the Federal Republic of Germany for comparison purposes.

4. Received January 31, 1994; accepted June 6, 1994.

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2. This discussion is based on an exchange rate of 1 US$ = 1.66 DM.
they are permitted to treat SHI patients. The office-based physicians are linked in regional associations of SHI physicians, which in turn are combined throughout Germany in the Federal Association of Regional Physicians Organizations. These organizations are the negotiating partners vis-à-vis the health insurance funds. The duties (2) of the regional associations of SHI physicians consist of guaranteeing the ambulatory care of the insured people, monitoring the economic efficiency of measures carried out, and managing the payment of practitioners.

Every year the health insurance funds and the regional associations of physicians negotiate a regional budget (Fig. 1). The health insurance funds turn over the bulk of the revenues they collect from employers and employees to the regional associations of doctors. These associations reimburse their members for the ambulatory services they provide on the basis of a fee schedule. The role of the physicians’ associations as payers is unique to Germany.

However, an expenditure cap has been imposed on reimbursement for the services the physicians provide to patients (5, 6). The cap links the reimbursement that ambulatory-care doctors receive for each service to the number of services rendered by all practitioners: the higher the volume, the lower the payment per claim, and vice versa.

**Inpatient sector (hospital).** Before the Health Care Reform Act, there was a dual approach for the financing of hospitals: Investments for hospitals were paid for by the state; working funds were supplied by the SHI funds (Fig. 1). To finance the working expenses, the health insurance funds and the individual hospital negotiated an agreement on average nursing costs per day and per patient for the following year. The nursing costs contain all routine costs such as accommodation costs, medical and nursing care, laboratory costs, and so on. In September 1992 the average value was US$ 223 per patient per day (range $120–600, depending on the type of hospital). The health insurance funds paid this sum in accordance with the number of occupied beds at the hospital. This system was an invitation to keep patients hospitalized as long as possible to achieve a higher utilization of capacity. It will be changed by the new Health Care Reform Act.

**Expenses of the SHI System**

In 1970 the expenditure of the SHI system (7) was US$ 15 billion (Fig. 2). By 1992 it has risen to US$ 106 billion (8), a sevenfold increase. To finance these high expenditures, the contributions of the insured persons had to be successively increased; nonetheless, there was a deficit of about US$ 5.5 billion in 1992 (8). For 1993 a deficit of US$ 6.6 billion was expected (8).

The proportional expenditures of the statutory health insurance system can be seen in Fig. 3. One-third of total expenditure is dedicated to the hospital sector, which in 1992 rose by 10.3% above that of the previous year. Laboratory costs accounted for ~US$ 1.2 billion in this sector. Another one-third goes to the practitioner sector (physicians and drugs), an amount that increased by 9–10% from the previous year. Reimbursement for laboratory tests in this sector amounted to ~US$ 1.6 billion (9). Overall, the SHI expenditures were 10.9% greater than in 1991 (8), whereas income in this period rose by only ~4%.

**The New Health Care Reform Act**

In an attempt to stop the overproportional increase in the health expenditure—which has existed in the SHI fund sector for several years—the Health Care Reform Act was enacted to take effect on January 1, 1993. Compared with earlier laws, this Act has led to drastic measures in the health sector.

An important objective of the Health Care Reform Act is a balance between income and expenditure. In accordance with the expected additional income of 3.1% for the SHI system in 1993, expenditures in the hospital budget, fees for doctors, administration expenses of the health insurance funds, and so forth are allowed to increase by only the same percentage. Only if this target is met will the contribution rates of the insured persons remain steady. Implementing these measures from the Health Care Reform Act should save ~US$ 6.6 billion in 1993 (10), which corresponds to the originally expected deficit for 1993.
Everyone involved in the health sector will pay for these changes, as illustrated by a few important points of the law:

1. The self-participation of patients in therapy costs was increased, e.g., for medication and hospitalization.
2. The principle of reimbursement of all costs from the hospital sector was abolished. This means that the hospital no longer automatically has all of its working expenses reimbursed; instead its budget could rise by only 3.1% in 1993.
3. As of 1995/1996, the total nursing costs will be replaced by, among other things, "DRGs" (Diagnosis-Related Groups) to shorten the periods of bed-occupancy in hospitals.
4. The carrying out of ambulatory operations was supported.
5. Total fees for practitioners (office-based physicians) could rise by only 3.1% in 1993.
6. The 1993 budget for prescription drugs was reduced to the amount for 1991.
7. The doctor's freedom to establish a practice was restricted.
8. The administrative costs for the statutory health insurance fund could rise only 3.1% in 1993.
9. The prices for all prescription-only drugs that do not have set reference prices were required to be lowered by 5% on January 1, 1993, and could not be changed for 2 years.
10. The proportion of drugs having set reference prices was extended to 80% of all prescribed drugs (only the reference price of the drugs is reimbursed by the statutory health insurance).
11. Laboratory expenditure in the practitioner sector must be reduced by 20%. The physicians' and health insurance funds were legally obliged to change the laboratory structure and reimbursement by December 31, 1993 (discussed later).

The legislative intervention by the Health Care Reform Act has already had massive effects. As Fig. 4 shows, expenditures in the first 6 months of 1992 rose by 11% relative to the previous year. By contrast, in the first half of 1993, expenditures had decreased by 2.7% from the previous year (11, 12). As a result of these regulations, the aimed-for economies have been achieved in almost all sectors, and in some cases—pharmaceuticals—even exceeded.

**Impact on Laboratories**

In 1993, the total expenditures for laboratory tests in Germany were ~US$ 3.3 billion, including tests in the hospital, practitioner, and private physician sectors. In the ambulatory sector, ~US$ 1.7 billion (9) was paid in 1992 to practitioners as remuneration for laboratory tests. This sum has increased by only ~11% since 1980, even though increasing mechanization in the laboratory, new analytes, and extended fields of indication have led to a continuous increase in the volume of tests. The laboratory tests are divided into three groups (see Table 1):

1. Basic investigations, including, e.g., urinary test strips, hematology tests, etc. These can be carried out by all physicians. Basic tests account for ~7% of laboratory fees (US$ 120 million, 1992), a percentage that has fallen slightly in recent years. Reimbursement for these tests is calculated in accordance with a fee schedule that was agreed upon between the SHI funds and the Federal Association of Regional Physicians Organizations. However, because of the cap placed on the sum available for all laboratory tests, reimbursement can vary within certain limits, depending on the total number of tests requested.
2. General investigations, including the methodically relatively simple laboratory tests, e.g., determination of enzymes and substrates, clotting factors, etc. These tests...
can be carried out by all practitioners, specialists, pedi-
atrians, and laboratory physicians. They can be car-
ried out in the laboratories of practitioners or in group
laboratories. In recent years the number of general in-
vestigations has increased by ~4% annually. The fees
for these tests in the practitioner sector were ~US$ 723
million in 1992 (9).

3. Special investigations, including above all method-
ically more complicated analyses, e.g., immunological,
serological, and bacteriological tests. These analyses
may be investigated by all laboratory physicians or by
doctors having documented specialist knowledge. The
number of special examinations is increasing by ~15%
annually. The fees for these tests was ~US$ 783 million
in 1992 (9). These tests are carried out especially by
laboratory institutes.

Practitioner’s laboratory. About 7000 to 10 000 gen-
eral and specialist practitioners have this type of lab-
atory, generally equipped with dry-chemistry-type sys-
tems. The number of practitioners’ laboratories is
decreasing. Almost all practitioners and internists are
additionally associated with a group laboratory.

Group laboratories. The group laboratory primarily
servers an association of practitioners, internists, and
other specialists with the aim of carrying out laboratory
tests as efficiently, rapidly, and reliably as possible with
the aid of modern automatic analyzers. Only “general
and basic tests” may be carried out in group labo-
ratories. On average, 200 doctors are associated with one
group laboratory at present, most of whom live in the
same region. In addition, a few large supraregional
group laboratories have several thousand members. In
all, there are ~220 group laboratories in Western Ger-
many. An average group laboratory processes between
800 and 1000 patients’ samples daily, carrying out
~4000–5000 tests on these samples.

The professional management of a group laboratory
must include a doctor (e.g., a specialist). Nowadays,
~80–90% of the normal clinical chemical tests in the
practitioner sector are carried out in group laboratories.
However, the hard price struggle between the group
laboratories has led to a concentration process in recent
years; this consolidation will be drastically accelerated
by the Health Care Reform Act.

Laboratory institutes. Germany has ~250 laboratory
institutes, which are headed by a laboratory physician
(comparable to a pathologist). The institutes have con-
centrated on the so-called “special investigations.” As a
rule, practitioners are not allowed to carry out these
investigations themselves; instead, they send the pa-
tients (or patients’ samples) to a laboratory physician.
The laboratory physician communicates the findings to
the practitioner requesting them and charges the health
insurance fund accordingly via the regional association
of physicians. Every laboratory physician must have
completed a study in medicine and another 5 years of
further education in internal medicine, microbiology,
immunology, clinical chemistry, etc. before taking the
laboratory physician examination.

The hospital laboratory. There are ~3000 hospital
laboratories, with the larger hospitals often having sev-
eral laboratories. The responsibility for laboratory ser-
vices in smaller and medium-sized hospitals is generally
held by the hospital specialists for internal medicine. In
the larger hospitals, the laboratory is frequently headed
by a laboratory physician or a clinical chemist. An esti-
ated 550 million laboratory tests are requested in the
hospital sector. In this sector, the laboratory tests are a
component of the nursing costs and are not calculated
separately. The only exceptions are the tests carried out
for private patients.

Quality Control

For work carried out in the laboratory, quality-control
requirements for 47 clinical chemistry and immunolog-
al analytes are laid down by law (13). Extension of
quality-control specifications to further analyses is
planned.

Quality control consists of internal and external qual-
ity control. Currently, for external quality control, par-
ticipation in two interlaboratory surveys per year is
obligatory. For each analyte the laboratory must have a
certificate of performance, which is valid for 1 year. For
internal quality control, the measurement of precision
and the separate measurement of accuracy are pre-
scribed. The results must be kept for 5 years.

Future Reimbursement to Practitioners

In response to the legal regulations in the Health
Care Reform Act, the health insurance funds and the
Federal Association of Regional Physicians Organiza-
tions originally agreed that, as of April 1, 1994, only a

<table>
<thead>
<tr>
<th>Test group</th>
<th>Examples</th>
<th>Average reimbursement US$/test</th>
<th>Reimbursement planned as of April 1994</th>
</tr>
</thead>
<tbody>
<tr>
<td>Basic investigations (obligatory for all doctors)</td>
<td>Urinary test strip, urinary sediment, hemogram, etc.</td>
<td>1.22</td>
<td>Single-test reimbursement, number of tests is limited, reduction of fees</td>
</tr>
<tr>
<td>General investigations (possible for all general practitioners, internists, etc.)</td>
<td>Clinical chemistry, complete blood count, clotting factors, etc.</td>
<td>1.95 (glucose, cholesterol, creatinine, enzymes, etc.)</td>
<td>Same as for basic</td>
</tr>
<tr>
<td>Special investigations (only with special permission)</td>
<td>Immunological serological, bacteriological tests, etc.</td>
<td>7.32 (RIA of thyroid hormones)*</td>
<td>Single-test reimbursement, reduction of fees</td>
</tr>
</tbody>
</table>

* Thyroid-stimulating hormone, triiodothyronine, thyroxine.
lump sum would be paid for basic tests and general investigations (14). Each doctor was to receive a lump sum per patient automatically, irrespective of whether the patients were tested or not. Only special assays from the fields of immunology or serology and a few other exceptions would continue to be reimbursed as single tests. Many experts feared, however, that the introduction of lump-sum payments without proof of services rendered would lead to a dramatic decrease in laboratory diagnostics in the practitioner sector as well as deterioration in quality. 

After massive criticism by numerous doctors, therefore, the Federal Association of Regional Physicians Organizations decided in January 1994 to annul this agreement and retain the procedure of reimbursement for individual tests. However, the number of tests performed by each group of doctors is to be limited, so that each doctor will receive—depending on his or her specialist group and number of patients treated—a certain quota of tests that can be carried out and submitted for reimbursement. These changes must be approved by the health insurance bodies, too.

Furthermore, the laboratory budget for practitioners is being reduced by ~20% to take into account the economies demanded by the legislators. At the same time the reimbursement for the individual tests was also lowered by, on average, 20% from the 1993 figures. These new arrangements come into effect on April 1, 1994. The discussion on the future reimbursement of laboratory tests appears to have accelerated the concentration process among group laboratories.

Consequences of the Health Care Reform Act for the Hospital Laboratory

A merging of laboratories will also take place in the hospital laboratory sector. Because of the budget limitations specified in the Health Care Reform Act, economies to be made in the hospital laboratory will mean that the smaller hospital laboratories in particular will have to either join together or combine with group laboratories or laboratory institutes from the practitioner sector.

In conclusion, the Health Care Reform Law has achieved its main objectives in the laboratory sector. In the practitioner area the reimbursement structure has been altered, and the total fees for laboratory tests have been reduced by 20% in favor of counseling activities; accordingly, a reduction of the same magnitude has been achieved in the reimbursement for tests (as of April 1994). An immediate effect has been a pronounced reluctance to invest in new instruments, both in the hospitals and the private laboratories. In the hospital sector, also, the limitation of the available budget has led to a more critical attitude when laboratory tests are requested.

Overall, these changes are expected to lead to a reduction in the number of tests, in response to demands from various sources. To what extent these economy measures deleteriously affect the quality of laboratory tests cannot be said with certainty until the relevant information of 1994 becomes available. With regard to the future, however, representatives of the medical profession have clearly expressed the view that the currently agreed-on reimbursement structure for laboratory tests must be replaced in the medium-term by a new structure better suited to the medical requirements. In the hospital sector, the introduction of DRGs in 1995/1996 will probably intensify the critical attitude regarding requests for laboratory tests and hence lead to a further reduction in the number of tests performed.

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References