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To: Dr. Joshua Lederberg, Professor and Chairman, Department of Genetics

From: James Theodore, M.D., Associate Professor of Medicine, Chief, Division of Respiratory Medicine

Subject: Effect of government regulation on health care costs

The question concerning the adverse effects of government regulation on the cost of health care delivery is not only pertinent, but one that requires careful investigation. In my view, there is no doubt that regulatory agencies contribute significantly to the rising costs for medical services. However, documenting costs which are directly the result of compliance with these regulations, in precise terms, is more difficult and would be an appropriate area for research.

I initially planned to comment on the adverse effects of Title 22, but realized it was unrealistic to focus on this statute alone as the sole cause of our problems at Stanford Hospital. (However, it is a major catalyst nonetheless).

The Joint Commission for Accreditation of Hospitals (JCAH) has long had the responsibility for determining the "standards" in hospitals and monitoring them for the purpose of "accreditation". If a hospital is found "lacking" and loses its accreditation, certain sanctions are imposed on it. Residency training programs (probably other training as well) within the institution are no longer "accredited". More drastically, payments from government sponsored programs are automatically stopped resulting in a considerable loss of income (Titles 18, 19, and 5 - I'm not sure what they are, but are probably tied into aspects of Medi Care, Medi Cal, and other government support of hospitals).

Title 22 (California Administrative Code) evolved in content to a large extent from criteria set forth by the JCAH. However, it is much more explicit in setting specific standards for hospitals in California. Furthermore, this statute gives the Department of Health in the State the power to license facilities on the basis of "standards" defined by the code. Whereas, JCAH has no real "legal power", but can indirectly effect a hospital adversely (e.g., no training programs, no government money), Title 22 empowers the State to "close you down" via the licensing mechanism.

Interestingly enough, Title 22 does not apply to State owned facilities (likewise, I believe County owned facilities), but only to private institutions. Therefore, all the hospitals and health facilities of the University of California system are exempt. Thus, a complex institution like Stanford Medical Center is considered in the same context as a 50 bed hospital owned by group of physicians in a small community.

To summarize at this point, Title 22 is one of the elements comprising a "syndrome" of regulatory "processes" which effect medical facilities. These would include JCAH, Medi Care, Medi Cal, health insurance carries (who take their lead for "payments" from the others) and various agencies empowered "to license". These


more visible elements of the syndrome are further complicated by imprecisely defined elements such as "consumerism", affirmative action and its enforcement, "informed consent", and a variety of other "sociopolitical" pressures which are often indeterminant at a given point in time.

With the above in mind, I would like to combine all those elements under the single heading of "regulation" for the purpose of discussion. Furthermore, since the regulations stated in Title 22 and JCAH are similar in most respects, they can be commented on as "one" with specific exceptions to be noted. The main thrust of these "codes" is the requirement for explicit and detailed written statements pertaining to organization, job discriptions, policies, discriptions of procedures, and "documentation" of everything and anything to demonstrate "compliance".

Regarding Respiratory Care Services (as defined by JCAH and Title 22) the area I am most familiar with, over 3000 man hours have been spent writing and collating material for every phase of the operations involved. Most of the work deals with trivia that delights bureaucrats, but has nothing to do with improving patient care. A major portion of time was spent for record keeping, filing systems, or documenting that manuals are "constantly reviewed", the files on the "maintenance history" of equipment are current, etc... etc...etc. The method of assessing the quality of these services is by "audit". This usually means the "inspector" sits in a room requesting "this file" or "that record" which "documents" compliance with the "code". In truth, the quality of patient care or the quality of services provided to patients can not be realistically determined in this fashion.

Apparently the hospital has established that the up coming JCAH and State (Title 22) inspection has top priority and "we must pass" to be accredited for the next 2 years. (Stanford warned in the past year and received only "one year extension"). With this emphasis over the past 3 or 4 months, one senses the enormous effort that has been given forth. If our service devoted 3000 man hours, by "multiplying" this figure by the number of other services, departments, etc., throughout the hospital the resulting cost in "man hours" must be astronomical.

How does one compute the direct cost for the man-hours being spent to comply with regulations? Even though it is said "time is money", placing a cost factor on this activity is difficult. Many "exempt" employees did the work on their own time, or other work was set aside during the regular working day in order to devote effort to "codes". Without actual figures for "overtime pay" or for additional personnel being hired to meet the additional load, a specific cost can not be readily placed. The analysis of these kinds of activities and the determination of an actual (rather than arbitrary) cost for them could be investigated.

Below, I have listed some specifics which may serve as possible "indicators" in determining "cost as a direct result of regulations" in Stanford Hospital. Where possible, I will show estimated costs in dollars. This list is not complete, but may be illustrative of the kinds of data base that may be of use in a future comprehensive research effort.
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1. Cost to Bring Facilities to "Code"

It is rumored (from a reasonable source) that Stanford Hospital expects to spend 5 million dollars just to bring the plant facilities up to "code" per JCAH and Title 22. It is Title 22 that produces most of the concern since it empowers the State to remove our "license" to operate. Loss of accreditation via JCAH results in the loss of training programs and income from government sources.

It would be difficult to determine how much is hospital "neglect" over the past 20 years or trivia related to code requirements. Even more difficult to determine will be the justification that this expenditure will actually improve the quality of care and patient safety at Stanford Hospital.

2. Relocation of Neonate Intensive Care Unit

The new "codes" require a given amount of space for each bed in this type of unit. How the square footage around each bed was actually determined for optimal patient care is not readily known.

Last year, Stanford Hospital had less square feet per bed in the Neonate ICU than permitted by code. Thus, the unit will be moved to new "temporary" space for 12 months while the current facility is reconstructed to meet the code requirement. The estimated cost for construction is $100,000 (I do not believe this is included in the 5 million dollars noted above. However, I don't know).

The Blood Gas Laboratory (part of Respiratory Medicine) provides service to this unit with a satellite laboratory within unit space. This lab will also have to be relocated to "temporary space". If the satellite Blood Gas Lab is outside the proximate area of the temporary unit, two more people will need to be hired to maintain the current level of service. Therefore an additional cost of $12,000 - $14,000 is required for the 12 month period for these two "FTEs". Furthermore, the "temporary" Neonate ICU will have 6 less beds for this period. This will result in a loss of income of approximately $120,000 from the decreased number of blood gas analyses that would have been done normally.

3. Escalators

In 1959 when Stanford Hospital was built, the hospital escalators met the State requirements at that time. Recently, the State code was changed (Title 22) and now the hospital must spend $120,000 to meet the new requirements for escalators.

4. Other "Relevant" Indices

   a. Legal: In the past, Stanford Medical Center had the equivalent of 1/2 full time lawyer. At present, the legal staff consists of 5 full time lawyers plus secretarial, etc., support. One of these lawyers however, works full time in the Personnel Office. All litigation is handled by outside law firms. Thus, our lawyers are primarily legal monitors in the Medical Center.

   I can not place a "cost figure" in this category, but with the "inhouse" and "outhouse" legal arrangement currently present it must be significant.

   b. "Room F-06" Chart Auditing: There are 4 full time nurses and 4 secretaries engaged in auditing charts to recover "charges" from Medi Care, Medi Cal,
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and possibly other "health providers".

In the past Medi Cal primarily, and the others as well, refused payment to Stanford for services rendered because of "non compliance" in billing practices. The "loop hole" used by these agencies was the "lack of documentation" by faculty physicians that services were actually rendered, and that these "direct services" were not part of teaching. (All medical schools are vulnerable to this ploy because of their teaching responsibilities and how training programs are devised).

The primary responsibility of this group of 8 people is to make certain that charges are "documented properly" on the chart, in compliance with the law.

There are other "groups of auditors" in the hospital for a variety of purposes. One of these is associated with the Quality Assurance Program (QAP) to ascertain the quality of care given patients. One full time person works for the Administration just to coordinate the activities of this program. The number of "staff" working in the Records Room, etc., to retrieve records and monitor them is unknown to me. This does not include physician time spent in writing up protocols for auditing specific diseases or in reviewing charts that "fall out" due to non compliance.

Evidence has been accumulating from elsewhere that these kinds of auditing programs have no effect on the quality of patient care given.

c. Legislative "Watchdog": As far as I know, there is only one full time position of this nature in the hospital. The specific role is to "watch for" new health related legislation coming from Sacramento and determine if it may have direct effects on the hospital. What other function this individual performs in the Administration is unknown to me.

d. Staff to Bed Ratio for Stanford Hospital: In 1962 there were 1170 people employed by Stanford Hospital which then had 480 beds. In 1978 there are approximately 3100 hospital employees with 638 beds. In the last 16 years there has been almost a 300% increase in staff for a 33% increase in beds. In 1962 the staff/bed ratio was 2.9, whereas in 1978 this ratio is 4.9.

Unfortunately, this data does not separate patient related staff from non patient related staff. Separation of these two groups of staff might be helpful in determining the increases which were the direct result of "regulatory processes". Those noted above in a, b, and c for example, could fall into this group.

3. Personnel Office and Miscellaneous: This could represent an extension of the point made in (d).

In 1962, the Personnel Office had 5 people on the staff. In 1978 there are now 35 people including a full time lawyer. The number working for the Medical School and those working for the hospital isn't known to me (I am told approximately 20 could be considered "hospital based"). Analysis of this type of unit should be of research interest in looking for cost factors that effect medical care costs.

Other similar type sections, which lend themselves to this kind of research, would include; the increase in employees and total costs found in the "Business Office and Data Processing", changes in the size and scope of the Administration and related staff, and others by simply thumbing through the Medical Center phone directory.
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Several weeks ago a "mock inspection" regarding JCAH and Title 22 was carried out through the hospital by an outside consulting team. This cost only $2000 - $3000. I include this "paltry sum" only to point out that this is the first bargain I've seen here, in comparison to the huge sums spent in the past for consulting services.

My comments to this point did not include additional costs, which may or may not be obtainable. In addition to the thousands of man hours spent on JCAH and Title 22, there are also the costs for paper, new files, storage space, construction related to filing and storage, and the endless copying at the "xerox machine". Spreading this over the entire hospital should result in a significant sum of money.

Summary:

I've attempted to present a reasonable argument, with some data included, that regulations and regulatory agencies contribute significantly to the high cost of medical provision. In most circumstances I feel certain they will have no effect in improving the quality of patient care. The costs incurred for compliance with regulations find themselves "buried" into the overhead and/or indirect cost categories of hospital budgeting. Regardless, they all get "calculated" into the bed rate and other patient related services.

Research into this area is needed, and if it can be done with reasonable accuracy it should be of real benefit to all concerned.

In closing, I wish to apologize for the length of this "note" and hope it will be useful. I feel the information is reasonably accurate and not distorted by emotionalism. The figures presented, in terms of money and personnel, should be close if not exact. I should state that some caution is warranted, since a significant portion of the "money figures" presented were extracted from "grape vine sources". Nonetheless, I am certain the whole discussion deals with a real and significant issue, and at best only represents the very tip of the iceberg. This further emphasizes the need for investigation.