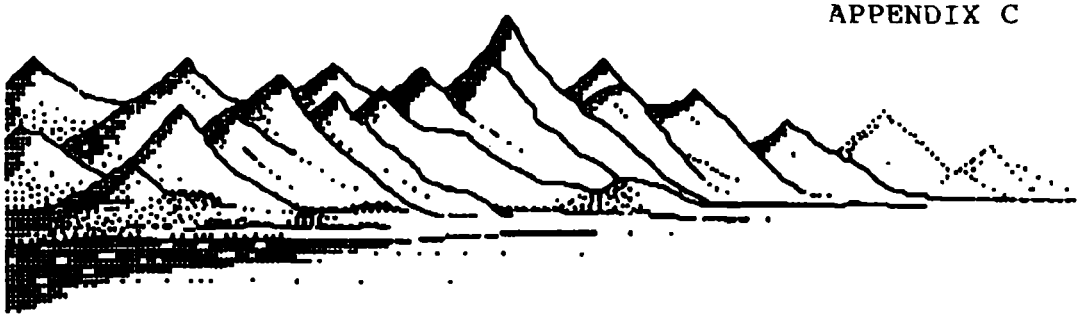
APPENDIX C



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May 5 1994

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To LINDA BERGTHOLD	From DAVID EDDY
Co. 202 463 8006	Co.
Dept.	Phone #
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Karen Hein
Professional Staff Member
Senate Finance Committee
FAX 202 228 5568

Dear Karen

Enclosed you will find two outlines. One defines "medically appropriate." The other describes the roles of the national health board and health plans in implementing the definitions. I tried to pattern the language for "medically appropriate" after the format in the Cooper-Breaux Bill, to simplify consolidation of the two drafts. (The Clinton plan does not try to define "medically necessary" or "medically appropriate.") I also tried to keep the language lean. Obviously there is a lot of background behind each item. However, instead of laying out all the details and explanations now, I will mention only the most important items you will want to keep your eyes on. The following observations are drawn from the article I am currently writing for JAMA.

1. First, notice the direction of the burden of proof. The first section says that a plan *must* cover *all* treatments and diagnostic procedures that can be shown to *meet* the criteria. However, the second section *allows*, but does not require, plans to *not* cover treatments and diagnostic procedures that *fail* to meet the criteria. This second section ("allow, but not force") is very important, because a lot of things we do in medicine do not meet even the first criterion (noninvestigational), much less the criteria of "effectiveness," "beneficial" and "appropriateness." If plans could *only* cover things that *did meet* the criteria, a lot of very common treatments would be eliminated from coverage and the practice of medicine would be thrown into chaos.

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The Clinton plan takes a different approach. It *excludes* things that can *not* be shown to be "medically necessary" or "medically appropriate" (see Section 1141 (a) (1), p 86). It might be able to get by with this because it fails to define either "medically necessary" or "medically appropriate," which has the effect of making the exclusion so ambiguous that no one would be able to figure out whether the exclusion was being honored or not. On the other hand, if the national board writes a regulation that specifically defines "medically necessary" or "medically appropriate," then Section 1141 (a) (1) in the Clinton plan could cause real trouble. For example, if the national board said things have to be noninvestigational to be medically necessary or medically appropriate, then the current language in the Clinton plan could force plans to not cover a lot of common practices. So watch out: if your definition of "medically appropriate" includes any criteria (as I hope it will), or if there is a chance the national board will specify criteria, then the direction of the burden must be as I have written it in my outline, not as the Clinton plan has it.

Fortunately, Cooper-Breaux takes the same approach as I do in my outline, saying that "An AHP is required to provide coverage of the uniform set of benefits only for treatments and diagnostic procedures that are medically appropriate" (Section 1302, b. (1), p 98). This is equivalent to my first section. Cooper-Breaux does not have my second section, which enables (but does not force) plans to exclude coverage for things that fail the criteria. I believe that it is very important to include this section, but plans could live without it if they absolutely had to (because silence implies flexibility). What we *must* avoid is forcing plans to not cover things that fail to meet the criteria. Medical practice would grind to a near halt if we did that. Indeed, it would be virtually impossible to enforce a clause that forbade plans from covering things that did not meet the criteria, because that would require that we assess every practice against the criteria, which is not feasible.

2. I like the way Cooper-Breaux uses "medically appropriate" and omits the words "necessary" and "necessity." That does three good things. First, those who want to cover abortions need "medically appropriate" but not "medically necessary." Second, by omitting "medically necessary," we do not have to define the difference between "necessary" and "appropriate," which I am unable to do. Third, the word 'appropriate" has a broad connotation—potentially encompassing lots of factors (like cost).

3. I redefined "medical condition." I think the Cooper-Breaux language is both oversimplified and cumbersome. It also appears to be tautological (a treatment is medically appropriate if it is indicated for a medical condition ... while a medical condition is something for which a treatment is indicated). Your two options are (1) to leave it undefined and trust the "common law" interpretations, or (2) try to define it right. The latter option is obviously preferable if it can be done fairly simply. The language I offer is about as simple as I can make it. It rests on common words such as disease, illness, injury and defect, which should be well understood. We need the second clause, about "a condition that if not treated could lead to a disease ..." in order to handle natural changes like estrogen deficiencies after menopause. Whatever language you use, some tests for unintended consequences you will want to apply are whether it will distinguish (a) reconstructive surgery and repair of congenital cleft lips from nose bobs and lip collagen implants, (b) breast implants following breast cancer surgery vs for cosmetic reasons, (c) treatment of osteoporosis from treatment of balding, (d) treatment of pituitary-caused short height from simply being short, (e) treatment of acute anxiety attacks from stage fright, and (f) nutritional supplements for phenylketonuria or cachexia from over-the-counter vitamins. I was not able to find a definition of "medical condition" in the Clinton plan. If the language for "medical condition" becomes an issue, I would be happy to do more work on it.

4. You will see that in my outline I have substituted the word "health intervention" where Cooper-Breaux uses "treatments and diagnostic procedures." I made this change because just using the two terms "treatments" and "diagnostic procedures" could cause a problem. It is true that in general all health interventions are of two basic types—those that *directly* affect health outcomes ("treatments"), and those whose effect on health outcomes is *indirect*—through providing information that can affect decisions about treatments (diagnostic tests). But by mentioning only "treatments" and "diagnostic procedures," the Cooper-Breaux language is ambiguous about things that do not fit clearly in either of those two categories, such as preventive services, screening tests, monitoring, support care and rehabilitation. You have a couple of options. (1) Use "treatment and diagnostic procedures" as in Cooper-Breaux, and rely on common sense to keep it from being too restrictive (2) Try to list all the main types of health interventions. The list would be something like "preventive services, screening tests, diagnostic tests and procedures, treatments (including drugs, devices and procedures), monitoring and surveillance, support care, reconstruction, and rehabilitation." (3) Pick one word such as "health intervention," "service," or "activity," and define it to cover everything. For example, elsewhere in Cooper-Breaux (eg, page 96), they use "healthcare

services," but without any definition. (4) Pick terms that are neutral in the sense that they do not have any current medical connotations that might confuse their interpretation. The Clinton plan uses "items and services". Although in the past, for other purposes, I have used the third approach and called all things "treatments" (followed by a three-line definition), I agree that that word could be misleading if it got separated from its definition. Thus if I were you I would either use a more general word like "health intervention," "practice," or "service" and define it to be very inclusive (as I did in (2) above), or use "items and services," as in the Clinton plan. For convenience, in my outline, I use the words "health intervention" as a place holder for whatever you decide to use.

5. Whatever term(s) you use for the things that will be covered, you will need to make it clear that the criteria and any resulting coverage decisions or guidelines are to be applied not to the health interventions themselves but to the application of the health interventions *for specific patient indications*. This is necessary because, as you know, a health intervention in the abstract (eg, an MRI) does not have *an* effectiveness or *a* harm, or even *a* cost, as though these were properties of the health intervention. Rather, the effectiveness (or harms or costs) of a health intervention depends acutely on the indication for which it is used. MRIs have high value for suspected brain tumors, but little value for diagnosing chest pain. Appendectomies have high value for patients with classic signs and symptoms of appendicitis, but little value for patients with diarrhea. The way plans will try to handle this is to either (1) cover the health intervention *only* if it is for specified indications that meet the criteria of noninvestigational, effective, and so forth; or (2) cover the health intervention for all indications, but design guidelines that discourage its use for inappropriate indications. To enable them to do either of these, we need to make it clear that a coverage decision, whether it is positive or negative, is *not* a decision about every possible use of the health intervention. You can see how I try to accomplish this in my outline. If that does not work, let me know, because this is important.

6. I left the definition of "investigational" unchanged. (The Cooper-Breaux language is very close to what I wrote for the Task Force.) The important elements to be certain to retain are:

   a. The existence of this criterion puts the burden of proof where it should be—consistent with "first, do no harm," the scientific method, and the Food, Drug and Cosmetic Act. This is a stricter burden of proof than we have traditionally applied to procedures and other

interventions that do not fall under the FDA, but we need it desperately if we are to reduce waste. If plans could cover *only* health interventions that met this criterion, they would be forced to throw out the large proportion of current practices. However, the direction of the burden that I describe in Section 1 of my outline, coupled with the "can exclude those that do not meet the criteria ..." clause in my second section (vs the "must exclude ..." in the Clinton plan), gives plans the flexibility to continue to cover interventions that would fail this specific criterion, but that are commonly used. Thus, as it is currently worded, this criterion *enables* plans to exclude treatments for which there is no convincing evidence of benefit (eg, PSA screening), but does not force them to (eg, surgery for early-stage prostate cancer).

b. This criterion asks for evidence not only of the existence of benefit but the *magnitude* of benefit. This is important conceptually, because it is information on the magnitudes of outcomes that enable comparisons between benefits and harms and between health outcomes and (costs). For example, this criterion will distinguish between a 1 in 1,000,000 increase in survival and a 1 in 10 increase in survival.

7. Cooper-Breaux combined "effective" and "safe" in one criterion. I believe that it is important to keep them separate. For my criterion of "effective" I changed that portion of the Cooper-Breaux criterion in one important way. In the Cooper-Breaux criterion for "effectiveness," there is a requirement that the health intervention in question be compared with other available alternatives. I have changed that to make the comparison with *no* treatment, instead "other available alternatives." Here is the problem with the Cooper-Breaux language. Suppose there is a disease that has a 10% five-year survival with no treatment. Treatment A is the current treatment; it increases survival to 50% but is very expensive, say $1 million. A new treatment, B, becomes available; it costs $10 and is *almost* as effective as A. Suppose we have five enormous randomized controlled trials that show conclusively that Treatment B increases survival (compared with no treatment) to 49.99999%. That is, it is worse than Treatment A by only 1 in 1 million. As Cooper-Breaux is now written, Treatment B would *not* be effective compared with Treatment A, and therefore would not pass the third criterion. This could make it very difficult to introduce treatments that could potentially save huge amounts of money while having a negligible effect on quality. I believe that that would be an unintended consequence you would want to avoid.

The Cooper-Breaux language for effectiveness and safety includes requirement that, to be effective the intervention must provide a clinically meaningful benefit. I am not entirely certain what Cooper-Breaux intends to accomplish with that requirement. Perhaps they are trying to get at the cost issue indirectly. For example, if we assume that a new treatment is more expensive than the available alternative, one might want to require that before it should be covered the new (more expensive) treatment should improve outcomes by "enough" (ie, a "clinically meaningful" amount) to justify the cost. If that is the intent, it is a messy way of handling the cost issue, for at least two reasons. First, it works only if the new treatment increases benefit and increases cost. It does not work for new treatments that are almost as effective, but much less expensive. Second, it leaves wide open the issue of just how big a health result must be to be sufficiently "clinically meaningful" to justify the costs. I have tried to write language that is more straightforward. As I have written it, the comparisons with no treatment will keep a cost-saving treatment in consideration. If it has less benefit than the current treatments, subsequent criteria will determine if its benefits are still large enough to outweigh the harms, and if any decrement in net benefit (this time compared with the best available alternative) can be justified by the lower costs.

8. To handle the issue of "safety," I have added a new criterion and called it "beneficial." The definition of "beneficial" is straightforward. To try to address the concerns of the abortion rights advocates, I have defined it in terms of the benefit "to the intended recipient," which is the mother. As for "safe" and "safety," although I understand the origins from the FDA, I am also concerned that virtually nothing is entirely safe, and a literal interpretation of "safe" would exclude virtually all practices. Cooper-Breaux is relying on common sense to avoid this. But why not take this occasion to clean up the language. "Relative safety" might work, but it is cumbersome. Thus I recommend that you use the terms that are now standard—that is, "beneficial effects" and "harmful effects," and let "beneficial" mean that the beneficial effects outweigh the harmful effects.

9. Obviously the most controversial criterion of "medically appropriate" will be the last criterion, which I labeled "appropriate." The idea behind "appropriate" is that when there are any limits on resources, whether imposed implicitly by the marketplace (eg, managed competition) or explicitly by caps on premiums or capitation, using resources to provide treatments that have very low-benefit relative to their costs means that those resources will not be available for other treatments that would have provided much greater benefit. I am assuming that we can

all agree that, if resources are truly limited, and if we had to choose between spending $10 million on one disease to prevent 100 deaths vs spending $10 million on another disease to prevent 10 deaths, we would all prefer to spend it on the first disease. If that is agreed, then we need to give plans language that will enable them to do it. The language I have proposed for this criterion is about as fuzzy as I can get, to try to accomplish what we need without forcing politicians to face the cold hard acts about the limits on healthcare costs. A more accurate term for this concept would be "cost-effective," but that term seems to be too hot to handle. Thus I have substituted a fuzzier term, "appropriate." To further avoid raising red flags I have also chosen rather flaccid language to define what we mean by "appropriate." My hope is that this language will be acceptable to politicians, yet still give plans what they need to proceed to maximize quality within limited resources. I believe that this language will work for plans, especially after I and others publish papers on how to implement this criterion. I could provide "subcriteria" for this criterion, but it is probably best to keep the language in the legislation as simple as possible, while still giving health plans what they need.

The most important point to keep in mind when you think about this criterion is this: If you have *only* the first four criteria (medical condition, noninvestigational, effective, and beneficial), without the fifth (appropriate, [or "[redacted]"]), which is the way the Cooper-Breaux bill now reads, you will *force* health plans to cover treatments that have *any* benefit, no matter how small, at *any* cost, no matter how large. This will wipe out any possibility of simultaneously controlling costs while increasing quality. Therefore, if *you* can *not* include the fifth criterion, then it is best to drop *all* the others, and leave the term "medically appropriate" undefined (as the Clinton plan does). To include the first four criteria by themselves would imply that they constitute a complete list of the criteria that must be met, which has the effect of prohibiting plans from considering costs. At least the general term "medically appropriate," without any definition at all, is fuzzy enough to allow plans to consider costs, albeit under the table.

Whatever language you end up with, here is a test you will want to apply to determine whether your language has any "unintended effects." Call it the "Eddy's first test." (I have a few others.) Imagine that there is a new treatment that, compared with the available alternatives, improves survival by one in a million but that costs $1,000,000. Will your language force health plans to cover it? The Cooper-Breaux bill would, because the treatment I just described does have benefit (one in a million), and therefore satisfies all their criteria. There is nothing in the Cooper-Breaux language that allows a health plan to *not*

cover something just because of its high cost, even if that $1,000,000 we would save by not using the new treatment could be used to prevent 10,000 underprivileged children from dying of, say, lead poisoning.

10. I did not address the issue of paying for "routine care" for treatments that are "investigational." Both the Cooper-Breaux and Clinton plans have the right idea, but the wording could be sharpened. I can say more about this if you want to get into it.

11. With regard to the roles of the National Health Board vs the Health Plans in implementing the coverage language, I like the general responsibility given to the National Health Board in the Clinton plan (section 1151(a), p 88), and made it the center of my first point (#1). I have amplified on it a bit, primarily to clarify that any decisions not made by the National Health Board fall to plans (or alliances, if they exist and want the authority). By the way, for the record I think it is very important to keep the alliances or HIPCs, and I think they should be given the authority to set coverage policies and guidelines. They probably will not choose to exercise that authority, but there could easily be occasions where regional policies will be needed, and the alliances will be the best place to make them.

That ends my comments on the language for and implementation of the coverage policies. I would like to close by offering some recommendations on some features of the Cooper-Breaux plan that you did not ask me about. If any of these parts are used in your bill, you will need to address them.

1. On page 100, lines 12 ff, the Cooper-Breaux plan says that a drug, biological or device that has been found by the FDA to be safe and effective under the Federal Food, Drug and Cosmetic Act will be considered to meet the criteria of noninvestigational, effective and safe that determine medical appropriateness. That is fine. However, it is important to note that FDA approval does *not* consider financial costs. Therefore if my fifth criterion of "appropriate" stays in, which I believe it must, you must make it clear that FDA approval does not necessarily mean that the last criterion of appropriateness has been met. The same point holds for off-label uses, discussed on page 101, lines 21 ff.

2. On page 104, lines 9 ff, the Cooper-Breaux plan lists types of "evidence" that can be used to make coverage decisions. The list includes "opinions of medical specialty groups and other

medical experts," and "evidence of general acceptance by the medical community." This is a disaster. It sets us back about 15 years in trying to improve the science base of medicine. The evidence has to be restricted to peer-reviewed studies. However, it is also important to note that studies can be peer-reviewed without necessarily being published. One example is studies conducted by drug companies and accepted by the FDA (and therefore peer-reviewed) but not published. Another example is reports based on registries and databases that are federally sponsored and periodically reviewed. This point is important, because a lot of negative studies are of excellent quality, but never published.

3. Finally, on page 105, the Cooper-Breaux plan refers to "unnecessary services in the context of cost sharing." This introduces the concept of "necessary," for the first time I believe, but does not define it. I believe that if this section is to be retained, the word "necessary" here (line 14) should be replaced by "not medically appropriate."

I hope this is helpful. I am sure that I have left some important things out, and that what I have included can be improved on. However, rather than trying to get it perfect, I decided it is better to get you something to begin with.

As I explained to you on the phone, I will actually be home for the next two weeks, until May 14. You can reach me directly on (307) 733 6758. Or you can call my regular number at (307) 733-9167. If you call that number, you will hear a message saying we are out of town. We are just saying that to discourage interruptions so that we can get some important work done (like yours). So just speak up when you answer our message. If I am at home I will pick up the phone. Otherwise, I'll return your call. And you can always fax us at (307) 733-5716. Thanks.

Best wishes

David

David M Eddy MD PhD
Professor of Health Policy and Management
Duke University

Enclosure

copy: Susan Foote

CRITERIA FOR MEDICAL APPROPRIATENESS FOR BENEFIT COVERAGE

1. A health plan is required to provide for coverage of the comprehensive benefit package only for health interventions that are "medically appropriate." A health intervention is considered to be "medically appropriate" if all of the following criteria are met.

A. Medical Condition. The health intervention must be for a medical condition. A "medical condition" is a disease, an illness, an injury, a genetic defect, or a biological or psychological condition that if not treated could result in a disease, an illness or an injury.

i. Health Intervention. A "health intervention " is any activity undertaken for a specified indication for the primary purpose of preventing, stabilizing, restoring, or improving a decrement in health outcomes caused by a medical condition. "Health interventions" include primary prevention, screening, diagnosis, treatments (including drugs, biologicals, devices, and procedures), support care, rehabilitation, and reconstruction. "Health intervention" does not include social activities that might have an indirect effect on health, such as housing, crime, education and employment. Nor does it include health interventions that occur as a normal condition of existence, such as food.

ii. Indication. An "indication" designates any feature of the patient or delivery-setting that could reasonably be expected to affect the health outcomes of a health intervention. Any reference to a health intervention is assumed to apply to a specific indication for that treatment or diagnostic procedure.

iii. Health Outcomes. A "health outcome" is an outcome that directly affects the length and/or quality of a person's life.

iv. Decrement in Health Outcomes. A "decrement" in health outcomes is said to exist for an individual if either (1) there is a decremental change in a health-related feature for the individual caused by a medical condition, or (2) the individual's original endowment for a feature lies outside the normal range to an extent that any reasonable person would call abnormal.

B. Not Investigational. There must be sufficient evidence on which to base conclusions about the existence and magnitude of the change in health outcomes resulting from the health intervention compared with the best available alternative, or with no health intervention if no alternative health intervention is available.

C. Effective. The evidence must demonstrate that the health intervention can reasonably be expected to produce the intended health result, compared with no health intervention.

D. Beneficial. The evidence must demonstrate that the beneficial effects of the health intervention to the intended recipient can reasonably be expected to outweigh any harmful effects of the health intervention, compared with no health intervention. OK

E. Appropriate. There should be good reason to believe that, compared with other available health interventions for this and other medical conditions, use of the health intervention can reasonably be expected to improve the total health of the population served by the Health Plan. ?

2. Exclusion From Coverage. Health plans can, but are not required to, exclude from coverage any health interventions that fail to meet any of the criteria that define "medically appropriate."

IMPLEMENTATION OF COVERAGE DECISIONS BY THE NATIONAL HEALTH BOARD AND HEALTH PLANS

1. The National Health Board may promulgate such regulations or establish such policies or guidelines as may be necessary to assure uniformity in the application of the comprehensive benefit package across all health plans. This includes but is not limited to

   a. specifying methods for determining whether specific health interventions meet the criteria for "medical appropriateness."

   b. making specific determinations about whether particular health interventions meet the criteria for "medical appropriateness."

2. Any regulations, policies, or guidelines promulgated by the National Health Board will be binding on all health plans, subject to any exceptions as specified or granted (see #3) by the National Health Board.

3. Individual health plans can request exceptions from regulations, policies or guidelines promulgated by the National Health Board. The National Health Board will develop procedures for hearing and granting requests for exemptions.

4. Any issues relating to application of the comprehensive benefit package not specifically addressed by regulations, policies or guidelines promulgated by the National Health Board will be left to the discretion of individual health plans.

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BENEFIT LANGUAGE: CRITERIA THAT WILL IMPROVE QUALITY WHILE REDUCING COSTS

David M Eddy MD PhD

SUBMITTED FOR PUBLICATION

One of the few things about health system reform everyone can agree on is that costs must be controlled but quality must not suffer. That can be accomplished, but it will require making controversial decisions about the coverage and use of practices—discouraging the use of practices that provide little or no value, and encouraging the use of practices that have high value.[1] An essential step in executing this strategy is to ensure that the legal language that determines which interventions will be covered as part of a benefit package not only supports but encourages these types of decisions.

Language of this type appears at two main levels. At the national level, most proposals for health system reform call for a "standard benefit package" that describes the broad categories of services to be covered by health plans. Examples of categories are "in-patient hospital services," "emergency services," and "ambulatory medical and surgical services." Within each of these categories there are hundreds of particular services, some of which should be covered and some of which should not. To make these determinations, any proposal for health system reform will need to specify specific coverage criteria—either in the legislation itself, or in subsequently developed regulations.

At a local level, the benefit language used by individual health plans is equally important. First, there might not be any national legislation. Second, even if there is, the language could well be very broad, providing little real guidance for making determinations about particular services. Third, even with detailed federal language, many if not most determinations will not be made at a national level, but will be left to individual health plans. For all these reasons, each health plan will need to have its own benefit language in the future, just as it does now.

For obvious reasons, the benefit language used by all the different parties should be as consistent as possible—preferably identical. This paper proposes specific language that can be used at either the national or local levels, and analyzes the benefit languages that are in the current national proposals for health system reform.

PURPOSES OF BENEFIT LANGUAGE

The design of benefit language should be determined by the purposes we want it to achieve. There are four main purposes, all of which result from the position of benefit language as one of the primary controls over the flow of money. The first is a direct result of the fact that the benefit language is a contract between health plans and their members on how the members' money will be spent. This purpose is to ensure that plans do not waste the members' money on nonmedical,

unproven, or ineffective practices. This is the traditional purpose of benefit language, and the purpose that has been the target of most of the legal challenges in the past.

The second purpose, which has evolved by default rather than by design, is to improve quality. Perhaps the most serious threat to the quality of care is the lack of good information on the effectiveness of many of the most common practices. To a great extent these gaps in knowledge exist because practices that have seductive biological theories are disseminated before the theories can be confirmed with clinical trials. The best way to correct this problem is to insist on good evidence of effectiveness before allowing a practice to be disseminated. Because it sits astride the flow of money, benefit language is in an excellent position to do this. If good evidence of effectiveness is made a requirement for coverage of a practice, that act would have the same effect on procedures and tests as FDA approval does on drugs, biologicals and class III devices.

The third purpose of benefit language mixes the previous two roles in controlling cost and quality: it is to help plans achieve the seemingly contradictory objectives of controlling costs while simultaneously increasing quality. The benefit language must at least enable, and preferably should encourage and guide health plans to weigh the benefits gained by an intervention against the costs, and to ensure that resources are allocated to interventions in a way that provides the greatest possible benefit. If the benefit language does not enable plans to consider costs, or even worse, forbids them from considering costs, there is little hope for achieving the main objectives of health system reform.

Benefit language has one more function that is more diffuse but still critical; it is to serve as a role model for the other tools available to health plans for controlling costs while increasing quality—CME programs, guidelines, precertification, case management, utilization review, and clinical quality improvement. Because they specify an "all or nothing" funding decision, coverage policies by themselves are fairly blunt instruments for controlling cost and improving quality. Most decisions require a much lighter touch, and are better handled with methods that can address finer levels of clinical detail, that are more flexible, and that give individual practitioners more room for personal judgment. However, for obvious reasons it is critical that all these tools follow a consistent set of principles and criteria. Because it is written into contracts, the benefit language can be considered the "master clock" that sets the timing of all the others.

HISTORICAL CONTEXT

If benefit language is to serve all these functions successfully, it must contain certain features. These features are best understood from a historical context.[2] Current benefit language has evolved out of a struggle involving three main parties: the third-party payers, acting on behalf of their subscribers; providers, acting on behalf of their patients; and the courts, which are trying to resolve the disputes between the payers and providers. In the beginning there were few

disputes. When modern insurance programs were created in the 1940s they were designed by the hospital industry and medical professional organizations, not only to help people spread the financial risks of medical problems, but also to ensure that providers got paid. Given these origins it is not surprising that insurers were content to take the judgments of providers at face value, and the initial contracts contained no explicit requirements that treatments meet any test of "medical necessity." For the first two decades, the only limitations in contract language addressed very broad categories of covered services or specific diseases.

This began to change in the early 1960s when providers began to request payment for questionable services such as hospitalization for weight loss programs or to rest up after a fall. By this time the historical ties to hospitals and physicians had softened enough, and price competition between insurers had increased to the point that insurers were less willing to accept the judgments of providers without question, and began to deny payment for the more extreme cases. However, when insurers were taken to court, the courts sided with the patients, even in cases of obvious abuse, on the argument that the insurers had no contractual basis for withholding payment. To counter this, insurers responded by adding to their contracts clauses that limited coverage to services that were "medically necessary" or "medically appropriate." The terms were poorly defined, but carried the connotation that the services should be for truly "medical" problems, and should be known to be effective. Although these additions to contracts helped clarify the purpose and intended limits of coverage, they did not prevent insurers from losing in court. The courts' reasoning appeared to be that, although it was appropriate for an insurer to limit coverage based on "medical necessity," the courts considered a decision by a physician to use a treatment to be de facto evidence of necessity—even though some of the treatments were outlawed in the US.[2]

To address this, toward the end of the 1970s insurers further refined their contract language by specifying that "medical necessity" would be determined by the insurers themselves, and by clarifying that "medical necessity" explicitly excluded treatments that were experimental or investigational. These contracts have been a bit more successful, but have still failed to block payment for treatments that, outside of courtrooms at least, medical experts will admit are investigational or not "medically necessary." When courts ruled against the insurers they usually based their judgments on very specific details of the particular patient, the insurer's particular contract language, or the process used by the insurer to apply the contract to the particular patient. In most cases, the courts held out the expectation that if the language had been more precise, or more comprehensible to patients, or more consistently applied, the insurer might have prevailed. This said, it is also clear that the courts' sympathies tend to be with the patient; wherever the legal burden of proof might lie, the practical burden of proof has usually been on the insurer.

This history identifies several requirements that benefit language must fulfill if it is to achieve its intended purposes. First, the language must be as clear and precise as possible. This is required to help ensure that members understand the motivation for and limitations of the coverage policy, that the language is applied consistently, and that courts can trace the rationale for particular decisions. One immediate consequence of this is that simply using terms such as "medically necessary" or "medically appropriate," without specific criteria to define them, will not suffice. At best, these terms are placeholders for more refined definitions that will need to be provided at a later time. A second lesson is that the language must reflect a motivation to serve the interests of the members. It is their money that is being processed and their care that is being affected. The language must have enough teeth to ensure that members' money is not being wasted, that individual patients will truly benefit from the treatments they receive, and that the plan's membership as a whole will derive the greatest benefit possible from the pool of financial resources the members have made available to the plan. Third, the language should be as consistent as possible with any existing federal legislation—in particular with the FDA's criteria for approving drugs, biologicals and devices. Fourth, if the language is to achieve all three of its purposes it must require an explicit evaluation of the evidence of an intervention's effectiveness, the balance between its benefits and harms, and its financial costs. On the last point, in order for plans to be able to lower costs while increasing quality, the benefit language must enable them to identify and reduce the use of interventions that have low value and are currently overused, and to increase the use of interventions that have high value and are currently underused.

TEST QUESTIONS

It is obvious that the last feature will be the most controversial, and achieving the twin objectives of simultaneously controlling costs and increasing quality will be the real challenge for any proposed language. Designing the parts of the language that address these objectives will be like operating on the brain stem—any tiny jiggle in the wrong direction could destroy everything or, as those who actually draft national legislation like to say, "could have unintended consequences." To help ensure that any language that is developed will actually accomplish the intended purposes, and not cause any unintended consequences, it is helpful to describe three hypothetical questions that will test the language's effects.

Imagine the following: There is a disease, cancer of the eyelid, that if untreated has a long-term survival rate of 10%. Cancer of the eyelid is very common, affecting 10% of all people sometime in their lives (which means that any decisions about its treatment will have large health and economic consequences). The current treatment, Treatment A, provides a 50% survival rate, and costs $100,000. There are two new treatments. Treatment B increases survival to 50.000001, and costs $1 million. (Out of a million people treated, it cures one more patient.) Treatment C has a long-term survival of 49.999999 and costs $1. (Out of one million people treated, it cures one less patient.)

The test questions are:

1. Will the benefit language force health plans to cover Treatment B?

2. Will the benefit language enable health plans to cover Treatment C?

3. If health plans can cover Treatment C, will the benefit language enable them to not cover Treatments A and B?

Given the extreme numbers I have chosen for the test questions, if there is to be any hope for controlling costs while improving quality, the answers to all three of these questions must be "yes."

A CAVEAT

A final point to be made before launching the discussion of the proposed language is that the discussion will at times become quite tedious, turning on a word or two. Readers who have responsibility for writing, interpreting or applying coverage language in health plans will appreciate the importance of points that to others might appear absurdly detailed. Other readers might be fascinated by the highly leveraged effects of nuances in phrasing, or amused by the unexplained and seemingly arbitrary differences in the languages proposed in different bills. What everyone should understand is that, while the national debates fly over employer mandates, premium caps and tax deductibles, the words that define what benefits are covered will have a far greater effect on what practitioners can and cannot do in their daily practices. In a $1 trillion-a-year industry, the definition of a term such as "medically appropriate" can easily swing $100 billion worth of tests and treatments. It is well worth our time to think about this very carefully.

COVERAGE POLICY

The following language is proposed to achieve the four functions and pass the three test questions. For convenience, the essential parts are in bold font.

1. **A health plan is required to provide for coverage only for health interventions that are "medically appropriate." A health intervention is considered to be "medically appropriate" if it meets all of the following five criteria.**

   A. **Medical Condition. The health intervention must be for a medical condition. A "medical condition" is a disease, an illness, an injury, a genetic defect, or a biological or psychological condition that if not treated could result in a disease, an illness, an injury or a defect.**

B. **Not investigational. There must be sufficient evidence on which to base conclusions about the existence and magnitude of the change in health outcomes resulting from the health intervention, compared with the best available alternative, or compared with no health intervention if no alternative health intervention is available.** If such evidence exists, the health intervention is considered "not investigational." If not, the health intervention is considered "investigational."

C. **Effective. The evidence must demonstrate that the health intervention can reasonably be expected to produce the intended effect on health outcomes, compared with no health intervention.** If this condition is met, the health intervention is considered "effective." If not, the health intervention is considered either "ineffective" (if it has no harms) or "harmful" (if it does have harms).

D. **Beneficial. The evidence must demonstrate that, for the intended recipient, the beneficial effects of the health intervention on health outcomes can reasonably be expected to outweigh any harmful effects of the health intervention, compared with no health intervention.** If the benefits of an intervention are judged to outweigh its harms, the intervention is considered "beneficial." If the beneficial outcomes of the intervention only equal its harmful outcomes, it is considered "equivocal." If its beneficial outcomes are outweighed by its harmful outcomes, it is considered "harmful."

E. **Appropriate. Compared with the next best alternative intervention, or with no intervention if no alternative is available, and considering the costs of the interventions and the benefits of alternative uses of resources, use of the health intervention can reasonably be expected to improve and not harm the total health of the population served by the health plan.** When determining whether a health intervention meets the criterion of appropriateness, there are three cases to consider, depending on the relative benefits and costs of the health intervention in question (the "target intervention") compared with the best available alternative, or with no intervention if there is no alternative (hereinafter called the "alternative intervention").

   i. The target intervention has equal or greater benefits, and equal or lower costs than the alternative intervention: In all such cases the target intervention is considered appropriate.

ii. The target intervention has lower benefit but also lower cost than the alternative intervention. The target intervention is considered appropriate if resources saved by using the target intervention instead of the alternative intervention could be applied to other health interventions so as to produce greater total benefit to the members of the Plan. If this condition holds, the appropriateness of the alternative intervention should be reevaluated.

iii. The target intervention has higher benefit and higher cost than the alternative. The target intervention is considered appropriate if allocating the resources to the target intervention would not prevent the use of other health interventions, possibly for other medical conditions, that could be expected to provide greater total benefit to the members of the health plan.

2. Exclusion From Coverage. Health plans are permitted to, but are not required to, exclude from coverage any health interventions that fail to meet any of the criteria that define "medically appropriate."

3. Definitions

A. Health Intervention. A "health intervention " is any activity undertaken for a specified indication for the primary purpose of preventing, stabilizing, restoring, or improving a decrement in health outcomes caused by a medical condition. Types of health interventions include prevention, screening, diagnosis, treatment, monitoring, surveillance, support care and rehabilitation. "Health intervention" does not include social activities that might have an indirect effect on health, such as housing, education and employment. Nor does it include interventions that occur as a normal condition of existence, such as food.

B. Indication. An "indication" designates any feature of the patient or delivery-setting that could reasonably be expected to affect the health outcomes of a health intervention. Any reference to a health intervention is assumed to apply to a specific indication for that intervention. For the purposes of determining the medical appropriateness of a health intervention, "indication" usually refers to characteristics of the patient (eg, severity of symptoms, stage of a cancer, concomitant diseases). However, differences in such features as the setting in which a treatment is provided (eg, out-patient vs in-patient), the training of the provider, or the available support (eg, access to a crash cart) could also represent different indications. Because the effectiveness of a treatment can be different for different indications, evidence that a treatment meets the five criteria for one indication does not necessarily mean that the treatment meets the criteria for all indications. When evaluating the medical appropriateness of a health intervention for a particular indication,

the five criteria must be met for that indication or for an indication that can reasonably be considered essentially similar.

C. **Health Outcomes. A "health outcome" is an outcome that directly affects the length and/or quality of a person's life.** Health outcomes are distinct from intermediate outcomes, such as shrinkage of a mass on x-ray, change in enzyme level, or change in a blood count. If the existing evidence for a health intervention pertains to intermediate outcomes, there must also be evidence that a change in intermediate outcomes caused by the intervention causes the desired changes in health outcomes.

D. **Decrement in Health Outcomes. A "decrement" in health outcomes is said to exist for an individual if either (1) there is a decremental change in a health-related feature for the individual, caused by a medical condition, or (2) the individual's original endowment for a feature lies outside the normal range to an extent that any reasonable person would call abnormal.** The concept behind this definition is that every individual is endowed with certain features that relate to health and health outcomes (eg, height, shape of nose, baldness, athletic prowess). Within a population, there is a range or spectrum for most health-related features. An example of a "decremental change in a health-related feature for an individual caused by a medical condition" is the development of angina from coronary artery disease. An example of an "individual's original endowment for a feature lying outside the normal range to an extent that any reasonable person would call abnormal" is a cleft lip. For the purposes of defining medical appropriateness, mere dissatisfaction with an individual's original endowment for a feature that is within the normal range (eg, short stature, a big nose), does not represent a decrement in health outcomes for that individual.

OBSERVATIONS

Several observations are important. They address features of the language that need emphasis as well as differences between the proposed language and the language in various proposals for health system reform now being considered by congress, especially the administration's Health Security Act (HSA) and the bill introduced by Representative Cooper and Senator Breaux ("Cooper-Breaux bill"). Even if these bills are changed with various markups, their initial forms are very instructive and will no doubt illustrate the types of issues that will continue to be important as the legislative debates sharpen. For convenience, I will refer to the language described in this article as the "proposed language," to distinguish it from the language in the HSA, the Cooper-Breaux bill, and other bills.

Burden of Proof

First, notice the direction of the burden of proof. The first part (No. 1) of the proposed language specifies that a plan *must* cover all interventions that can be shown to meet the criteria. However, the second part (No. 2) *allows*, but does not require, plans to *not cover* interventions that *fail* to meet the criteria. The need to allow plans to not cover interventions that fail the criteria for "medically appropriate" is obvious. The distinction between "allow" and "require" is equally important because many medical practices do not meet even the first criterion of "noninvestigational," much less the criteria of "effectiveness," "beneficial" and "appropriateness." If health plans were *required* to deny coverage for things that *did* not meet the criteria, many common health interventions would be eliminated from coverage and the practice of medicine would be forced to a near halt. Furthermore, if the second part did not exist, in theory at least health plans could be forced to demonstrate that every intervention that they covered met the criteria, which would be a practical impossibility.

The administration's Health Security Act comes dangerously close to creating that very problem. "The Comprehensive Benefit Package does not include an item or service ... that is *not* medically necessary or appropriate" (Section 1141 (a) (1) p 86).[3] By itself, this exclusion will make the comprehensive benefit package both very difficult to define and potentially very small, depending on the precise criteria used to define "medically necessary or appropriate." This clause does not expressly forbid plans from covering interventions that fail to meet the test of medically necessary or appropriate, but they would have to do so outside the comprehensive benefit package, and there is no formal clause in the HSA that allows them to do that. Furthermore, the implication is that such additions would be considered and charged for as a supplemental health benefit policy, which is defined elsewhere (Section 1421(b)(1)(A)(i) p 238)[3] as "coverage for services and items not included in the comprehensive benefit package." A practical example of the problem is that depending on the definition of "medically necessary or appropriate," plans could potentially require supplemental insurance to cover a treatment such as radical prostatectomy for early-stage prostate cancer.

The only thing that prevents the language in the HSA from throwing medicine into chaos is that, as it is currently written, the HSA fails to define either "medically necessary" or "medically appropriate." This has the effect of making the exclusion so ambiguous that no one would be able to determine whether a particular intervention met the exclusion or not. On the other hand, if the national health board that would be created by the HSA writes any regulations that specifically define "medically necessary" or "medically appropriate," then Section 1141(a)(1) in the HSA could cause important problems. For example, if the national health board said that to be medically necessary or appropriate health interventions had to be noninvestigational, which is a logical thing to say, then the current language in the HSA would prohibit health plans from covering many practices that are commonly used but for which there is no good evidence of effectiveness. The

critical point is that if the coverage language includes any specific criteria, or if there is a possibility that other organizations such as a national health board will specify criteria, then the direction of the burden of proof must be as written in the proposed language.

The Cooper-Breaux bill takes the same approach as the proposed language, saying that "An AHP [Accountable Health Plan] is required to provide coverage of the uniform set of benefits only for treatments and diagnostic procedures that are medically appropriate" (Section 1302, (b) (1) p 96).[4] This is equivalent to the first item in the proposed language. The Cooper-Breaux bill also specifies that "health plans shall not be prevented from providing coverage of a treatment that has not been determined ... to be medically appropriate" (Section 1302(a)(2)(E), p 96),[4] which corresponds to the second item in the proposed language.

As it is currently written, the bill submitted by Senators Chafee, Dole and others (S 1770)[5] is the most dangerous. It not only specifies that an item or service should *only* be covered when it is medically necessary or appropriate (Section 1301(b), and Section 1301(d)(1)), but it also goes on to specify that to be medically necessary or appropriate the item or service must be "noninvestigational," "effective" and "safe." Because so many interventions fail to meet the test of noninvestigational, this could be very disruptive to medical practice. The only possible escape valve in the bill is a subsequent provision for "binding arbitration evidence": "the evidence that may be used in making coverage decisions under a binding arbitration process ... includes ... opinions of medical specialty groups and other medical experts ..." (Section 1301(3)(5). Assuming that this provision for binding arbitration applies to coverage decisions in general and not just to those that are contested and come to binding arbitration, it is clearly broad enough to justify virtually all current practices. But this precision also raises very serious problems of a different sort: It undoes the intent of requiring evidence of effectiveness and safety in the first place, it contradicts the standard of evidence used by the FDA, and it undoes several decades of progress in evidence-based decisionmaking.

Medically Appropriate

The proposed language focuses on medical appropriateness, and purposefully omits any reference to "medically necessary" and "medical necessity." The main reason is that I have not been able to identify any single set of definitions that is widely accepted and that clearly distinguishes between "medical necessity" and "medical appropriateness." This is despite (or perhaps because of) the fact that the two terms are widely used in both contract language and academic articles, and are widely interpreted by the courts.[2] To include both terms, as in "medically necessary and appropriate" would imply that there is an important distinction between them, which I have not been able to discover.

Of the two terms, I prefer "medically appropriate" because it appears to include "medically necessary" (can anyone think of an intervention that is necessary, but not appropriate?), and

because in most usages it has a broader connotation—potentially encompassing the full range of factors that should be considered when making coverage decisions, such as the setting in which an intervention is being provided, the magnitude (not just existence) of its benefit, the extent to which its benefits outweigh its harms, and its costs. It is important to understand, though, that the term is merely a label for a concept that is defined in the proposed language by the five criteria. The fifth criterion in particular makes clear the intent that all pertinent factors, including costs, should be considered.

The administration's HSA uses "medically necessary *or* appropriate," but does not define either term. The Cooper-Breaux bill is similar to the proposed language, in that it refers only to "medically appropriate." It does specify criteria for determining whether an intervention is medically appropriate. Those criteria differ from the five criteria in the proposed language in a few important ways, which will be discussed below. The Chafee bill uses "medically necessary or appropriate," which matches the HSA, but defines the term with three criteria that are very similar to those in the Cooper-Breaux bill. Just to complete my case there there is no discernible meaning behind the terms, I will point out that the bill submitted by Senator Wellstone (S 491) uses "medically necessary *and* (not "or") appropriate," with no defining criteria.

Medical Condition

The intention of this criterion is to define the set of interventions that should properly be paid for from public funds, from interventions that, although they might be delivered by healthcare providers in healthcare facilities, are more a matter of personal taste than a medical problem, and therefore do not justify use of public funds. The criterion and its accompanying definitions are designed to distinguish, for example, between (a) repair of congenital cleft lips vs nose bobs, (b) breast reconstruction following cancer surgery vs breast implants for purely cosmetic reasons, (c) treatment of osteoporosis vs treatment of balding, (d) treatment of short stature due to pituitary deficiency vs treatment for simply being short, (e) treatment of acute anxiety attacks vs stage fright, and (f) nutritional supplements for phenylketonuria vs over-the-counter vitamins.

The proposed definition of "medical condition" rests on common words such as disease, illness, injury and defect, which are either well understood or which, if they do appear to overlap (eg, "disease" and "illness") are at least consistent. The definition of "medical condition" does contain a clause that extends the definition beyond current diseases, illnesses, injuries and defects, to include "a condition that if not treated could lead to a disease ...." This extension is required in order to address natural biological changes that are not by themselves diseases but that could benefit from treatment to prevent diseases or injuries. For example, neither pregnancy nor estrogen deficiency after menopause is a disease. However, we want to cover their management or treatment because, if not properly managed, they could lead to diseases (eg, preeclampsia of pregnancy or prematurity of the infant) or to injuries (eg, hip fracture from osteoporosis). The

proposed language is careful to distinguish between natural changes that could lead to diseases, illnesses or injuries, such as those just listed, from natural changes that do not lead to diseases, illnesses or injuries, such as baldness. If a treatment for "aging" is ever developed, we will need to revisit these definitions.

The administration's HSA does not include any terms or criteria that attempt to distinguish between a medical condition and a nonmedical condition. Instead, it lists specific types of services (eg, in-hospital services, services of health professionals, and ambulance services), and for some of these categories describes some limitations that have the effect of defining the boundaries of coverage. For example, the service category "out-patient rehabilitation services" contains the limitation that "such services [must] restore functional capacity or minimize limitations on physical and cognitive functions as a result of illness or injury" (Section 1123 (b)(., p 66).[3] Surgery and other procedures performed solely for cosmetic purposes are specifically excluded unless they are "required to correct a congenital anomaly or required to restore or correct a part of the body that has been altered as a result of accidental injury [or] disease" (Section 1141(b)(2) p 87).[3] This approach enables greater precision, but requires that the coverage criteria list and describe in detail all categories of covered services.

The Cooper-Breaux plan uses an approach similar to the proposed language. "The term 'medical condition' means a disease, illness, injury, or biological or psychological condition or status for which treatment is indicated to improve, maintain, or stabilize a health outcome or which, in the absence of treatment, could lead to an adverse change in a health outcome" (Section 1302(b)(1)(A)(ii) p 96).[4] However, the qualifier "for which treatment is indicated" appears to be tautological: A health intervention is medically appropriate if it is indicated for a medical condition, while a medical condition is something for which a health intervention is indicated. To avoid possible confusion about which comes first, the medical condition or the intervention, the proposed language does not include this qualifier.

Health Intervention

One of the most awkward features of any language is to choose a term for the "things" that are being covered. The proposed language uses the term "health intervention." The Health Security Act and the Chafee bill use "items and services." The Cooper-Breaux bill uses "treatments and diagnostic procedures." Other possibilities include "services, "treatments," and "health activities."

With respect to the Cooper-Breaux plan, just using the two terms "treatments" and "diagnostic procedures" could cause a problem. It is true that, in general, all health interventions are of two basic types—those that directly affect health outcomes ("treatments"), and those whose effect on health outcomes is indirect—through providing information that can affect decisions about treatments (diagnostic tests). However, by mentioning only "treatments" and "diagnostic

procedures," the language in the Cooper-Breaux bill is ambiguous about things that do not fit clearly in either of those two categories, such as preventive services, screening tests, monitoring, support care and rehabilitation.

There are three main ways to resolve this issue. One is to use terms that have well known connotations, such as "treatment and diagnostic procedures" and rely on common sense to keep them from being too restrictive. Another is to try to list all the main types or uses of health interventions. Such a list might be "prevention, screening, diagnosis, treatment (including drugs, devices and procedures), monitoring, surveillance, support care, reconstruction, and rehabilitation." A third option is to select one term such as "health intervention," or "service," or "activity," and define it to cover everything. That is the approach used in the proposed language. The choice of particular term is not critical, provided it is defined unambiguously. In the proposed language the term "health intervention" can be considered a placeholder to be replaced by a better term if one becomes obvious.

Indications

Whatever term(s) are used to describe the things that will be covered, the language must make it clear that the criteria and any resulting coverage decisions are to be applied not to the health interventions themselves but to the application of the health interventions for specific patient indications. This is necessary because a health intervention in the abstract (eg, an MRI) does not have *an* effectiveness or *a* harm, or even *a* cost, as though those were properties of the intervention. Rather, the effectiveness (or harms or costs) of a health intervention depends acutely on the indication for which it is used. MRIs have high value for suspected brain tumors, but little value for diagnosing chest pain. Appendectomies have high value for patients with classic signs and symptoms of appendicitis, but little value for patients with diarrhea. Health plans can handle this either by covering the intervention only if it is for specified indications that meet the criteria of noninvestigational, effective, and so forth; or by covering the intervention for all indications, but designing guidelines that discourage its use for inappropriate indications. To enable health plans to do either of these, the benefit language should make it clear that a coverage decision, whether positive or negative, is a decision about the intervention for a specified set of indications, and not a decision about every possible use of the intervention.

Noninvestigational

The current benefit languages used by virtually all insurers, HMOS and government programs contain exclusion clauses for investigational interventions. These clauses are needed to keep health plans from having to use public funds to pay for anything that anyone might dream up (eg, psychomassage for Lyme disease). They are needed to ensure consistency with the Hippocratic oath ("first, do no harm"), the scientific method, and the Food, Drug and Cosmetic Act. They are desperately needed if we are to improve the quality of evidence available for medical decisionmaking, which means they are needed if we are to increase quality and reduce waste.

However, it is important to recognize that this criterion implies a stricter burden of proof than we have traditionally applied to procedures and other interventions that do not fall under the auspices of the Food and Drug Administration (FDA), and that many commonly used practices will fail this criterion if they were subjected to an FDA-type evaluation. The proposed language enables plans to exclude health interventions for which there is no convincing evidence of effectiveness or benefit (eg, PSA screening), but does not force them to (eg, surgery for early-stage prostate cancer). It is important to appreciate both that this is a lenient stance, and that if plans are really to reduce waste in medical practices they will need to be aggressive in applying this criterion.

Another important feature of this criterion is that it requires evidence not only of the existence of benefit but the magnitude of benefit. This is important conceptually, because it is information on the magnitudes of outcomes that enable comparisons between benefits and harms and between health outcomes and costs. For example, this feature is needed to distinguish between a treatment that increases survival by 1 in 1,000,000 and one that increases survival by 1 in 15.

The position of the administration's HSA on coverage of investigational treatments is difficult to interpret. The pertinent language begins in Section 1101(1), "The comprehensive benefit package shall consist of the following items and services ...(1) hospital services ..., (18) investigational treatments (described in Section 1128, pp 32,33)".[3] Subsection (a) of Section 1128 reads "COVERAGE - Subject to subsection (b), the items and services in this subsection are qualifying investigational treatments that are administered for a life-threatening disease, disorder, or other health condition (as defined by the National Health Board p 71)."[3] Subsection (b) reads "Discretion of Plan — A health plan may cover an investigational treatment described in Subsection (a) (p 71) at its discretion."[3] It appears that this clause gives health plans discretion to cover investigational treatments if they address life-threatening problems. The language in the Cooper-Breaux bill is similar to the language proposed in this article.

Both the administration's HSA and the Cooper-Breaux bill have clauses that specify that plans should cover the "routine medical costs" associated with the delivery of investigational treatments, if the treatment is being given as part of an "approved" research trial. The coverage of the costs of research on investigational treatments as well as specific criteria for determining when the evidence for an intervention is "sufficient" to base conclusions about effectiveness, and guidelines for when plans should be strict in applying the investigational criterion, are all important topics that need more discussion. I will address them in a future article.

Effectiveness

The idea of effectiveness is straightforward: Setting aside issues of harms and costs, does the intervention at least do what it is intended to do? The proposed language has two important features. First, the effect must be demonstrated in terms of improvements in health outcomes,

not intermediate outcomes. If the existing evidence documents an effect on intermediate outcomes, there must be additional evidence that relates changes in intermediate outcomes caused by the intervention, to an improvement in health outcomes. For example, it is not sufficient to show that a screening test can simply detect a condition; there must also be good reason to believe the determination will change treatment, which in turn will improve health outcomes.

The second important feature of this criterion is that, when determining whether an intervention is effective, the comparison should be made with *no* intervention, not to other available alternative interventions. The reason for this is well illustrated by a comparison with the Cooper-Breaux bill. In that bill, the criterion for "effectiveness" takes a different approach and requires that the intervention in question be compared with other available alternatives. The problem with that can be illustrated with the three test questions described previously. Recall that cancer of the eyelid has a 10% *five-year survival* with no treatment, that Treatment A increases survival to 50% but is expensive ($100,000), and that Treatment C, which costs only $1 is *almost* as effective as A, with a survival *rate* of 49.999999%. The criterion in the Cooper-Breaux bill requires that to determine if Treatment C is effective we must compare it with the available alternative, which is Treatment A. By that comparison, Treatment C would *not* be considered effective (in fact it is harmful because it allows one out of one million patients to die), which means it would not pass the third criterion, and it would fail the second test question. The proposed language, which requires that we compare Treatment C with no treatment, would find Treatment C to be effective. This would keep it "in the running" for coverage. Subsequent criteria would evaluate whether the magnitude of its benefit justifies any harms it might have, and whether compared with Treatment A, it is appropriate (ie, whether the tiny decrement in quality is justified by the large savings that could be reallocated to other interventions).

The HSA does not have any requirement for effectiveness, beyond whatever is implied by "medically necessary or appropriate." The Chafee bill's definition of effectiveness begins with the same language as in the Cooper-Breaux bill, but adds a closing phrase that the comparison can be made "with the available alternatives, or the patient's current health status." The effect of this is to permit a comparison with no treatment, which brings the Chafee bill's language into line with the proposed language.

The language for effectiveness in both the Cooper-Breaux (p 100)[4] and Chafee (p 92)[5] bills includes a requirement that to be effective the intervention must provide a "clinically meaningful benefit." The intention of that clause is not entirely clear. Possibly the two bills intend to use this clause to address the cost issue indirectly. For example, if a new health intervention is more expensive than the available alternative, a plan might want to require that before it should be covered the new (more expensive) health intervention should improve outcomes by "enough" (ie, a "clinically meaningful" amount) to justify the cost.

If that is the intent, it is an awkward way to handle the cost issue, for at least two reasons. First, it works only if the new intervention increases benefit and increases cost compared with the current intervention. It does not work for new interventions that are almost as effective, but much less expensive. For example, this clause would not enable coverage of Treatment C for cancer of the eyelid, because Treatment C does not provide a clinically meaningful benefit compared with the available alternative, Treatment A (in fact it has a *not* clinically significant *loss* in benefit).

The language in the Cooper-Breaux and Chafee bills also introduces an interesting asymmetry; the criterion leads to different conclusions depending on which treatment is being evaluated. If Treatment A is the current treatment and Treatment C is new, Treatment C would not be covered because it is not effective, and we would end up with Treatment A. Now suppose Treatment C is the current treatment and Treatment A is the new treatment to be evaluated. Treatment A would *not* be approved because, in comparison with Treatment C it does not providing a clinically meaningful benefit, and we would end up with Treatment C. The second reason the Cooper-Breaux language is awkward is that it leaves open the issue of just how big a health result must be to be sufficiently "clinically meaningful" to justify the costs. To avoid these types of problems, the proposed language takes a different approach to the issue of costs—addressing it directly through the criterion of "appropriateness."

Beneficial

The definition of "beneficial" is also straightforward; the intention is that the intervention's benefits outweigh its harms. As with the criterion of effectiveness, the proposed language focuses on health outcomes and specifies that the comparison should be with no intervention, rather than an alternative intervention. The easiest way to appreciate the need for the latter is to return to the test questions and imagine that neither Treatment A nor Treatment C has any harms. If we require that Treatment C be compared with Treatment A it will not be considered beneficial, because compared with Treatment A it has a lower benefit.

As with the issue of effectiveness, the HSA does not include any criterion of beneficial in its definition of "medically necessary or appropriate." The Cooper-Breaux and Chafee bills take a different approach to the comparison of benefits and harms, requiring that a treatment be "safe," apparently drawing on language in the Food, Drug and Cosmetic Act. Although there is merit in using the same terms as the FDA, there is the problem that virtually nothing is truly safe, and a literal interpretation of "safe" would exclude virtually all practices. The language in the Cooper-Breaux and Chafee bills appears to rely on common sense to avoid this. However, it seems appropriate to take this occasion to improve the language. "Relative safety" might work, because it implies a comparison between degree of safety (ie, lack of harm) and degree of benefit, but it is cumbersome. The proposed language is based on concepts that are now in common use—the idea of safety is replaced by an assessment of the harmful effects on outcomes of the

intervention, and "relative safety" is replaced by an explicit comparison of "beneficial effects" and "harmful effects."

Appropriate

By far the most controversial criterion of "medical appropriateness" will be the last one, which the proposed language labels "appropriate." This is the criterion that addresses the tradeoff between quality and cost and enables plans to discourage the use of or even deny coverage for treatments that have benefit, but whose benefit is determined to be too small to be worth the costs. Because it addresses costs, cost-effectiveness, and the allocation of resources, there is enormous fear of being associated with a criterion like this one, and it should be no surprise that none of the bills before congress include one like it. On the other hand, this is the criterion that enables the proposed language to pass the three test questions, and this is the criterion that must be present if providers are to be able to preserve or improve quality while controlling costs.

The idea behind "appropriate" has already been described;[1,6,7] when there are limits on resources, whether imposed implicitly by the marketplace (eg, managed competition) or explicitly by caps on premiums or capitation, using resources to provide health interventions that have very low benefit relative to their costs means that those resources will not be available for other health interventions that would have provided much greater benefit. The proposed language assumes that virtually everyone would agree that the three test questions should be answered "yes." If that is true, then the benefit language needs to enable health plans to make those choices. The proposed language for this criterion describes this concept in a straightforward way, making clear that the intention is to compare benefits to costs, and that it is not only acceptable but necessary to withhold coverage for treatments like Treatment B or Treatment A for cancer of the eyelid, if the additional benefit (compared with Treatment C) is too small to justify the cost. It uses words like "cost" and "resources" explicitly and honestly.

Although the theoretical basis for this criterion is clear,[1] the political support for it is virtually nil. Many people, especially those who will be held publicly accountable for endorsing the language, will find the proposed language to be too threatening. Therefore, although I feel strongly that we will eventually have to be honest with people about the need to allocate resources, I also recognize that the required leadership to accomplish that might not yet be present. On the theory that ambiguous language is better than no language, I offer substitute language that disguises the full intent but still leaves plans enough room to take the necessary steps to increase quality while controlling costs. The current language says "Compared with the next best intervention or with no intervention if no alternative is available, *considering the costs of the treatments and the benefits of alternative uses of resources*, use of the intervention can reasonably be expected to improve and not harm the total health of the population served by the health plan." Alternative wordings, roughly in order of decreasing clarity but also decreasing threat, are:

"Compared with the next best intervention or with no intervention if no alternative is available, *considering all pertinent factors*, use of the intervention can reasonably be expected to improve and not harm the total health of the population served by the health plan."

Or, to borrow a term from the Cooper-Breaux and Chafee bills,

"Compared with the next best alternative, or with no intervention if no alternative is available, *if there is a significant difference in costs of the interventions, the difference in benefit must be of sufficient clinical significance to justify the difference in costs.*"

Or,

"Compared with the next best intervention or with no intervention if no alternative is available, *any difference in clinical benefit must be appropriate to* any difference in financial costs."

Anyone who is nervous about introducing the idea of costs in benefit language will be tempted to delete this criterion on the belief that if the first four criteria are retained, most (four fifths?) of the value of the criteria will be retained. That is not the case. The criteria must be treated as a package. If the fifth criterion is deleted and if the first four ("medical condition," "noninvestigational," "effective," and "beneficial" [or "safe"]) are retained, which is the way the language in the Cooper-Breaux and Chafee bills now reads, the effect will be to force health plans to cover interventions that have *any* benefit, no matter how small, at *any* cost, no matter how large. That is, health plans would be forced to cover not only Treatment A but also Treatment B (the $1 million treatment) for cancer of the eyelid. Such language would eliminate any possibility of simultaneously increasing quality while controlling costs. Therefore, if there is insufficient courage or leadership to include the fifth criterion, then it is best to drop *all* the others, and leave the term "medically appropriate" undefined (as the administration does in the HSA). To include only the first four criteria would have the effect of prohibiting plans from considering costs. At least a general term such as "medically appropriate," without any definition or criteria at all, is ambiguous enough to allow plans to consider costs, albeit under the table. However, any plan that chooses this route must be aware that an undefined phrase such as "medically appropriate" will provide little defense in court.

<u>FDA Approval</u>

A condition we placed on the proposed language was that it should be consistent with existing federal laws and regulations, especially the Food, Drug and Cosmetic Act. The proposed language satisfies that condition, enabling, but not requiring, health plans to not cover interventions that are investigational, or not effective, or not beneficial (ie, which are not "safe and effective," to use FDA language). However, it is important to observe that the proposed language

is not equivalent to the FDA language for two important reasons. First, although the FDA can approve a drug or class III device for marketing only if it is shown to be safe and effective, the proposed language (as well as the language in the Cooper-Breaux and Chafee bills) would allow a plan to cover an intervention even if it did not meet the FDA's criteria of safety and effectiveness. Recall that this was necessary because there is insufficient evidence to document safety and effectiveness of many commonly used interventions, especially procedures and diagnostic tests. The second difference works in the other direction. If a drug, biological or class III device has been found by the FDA to be safe and effective, that does not necessarily imply that it will meet all the criteria for medical appropriateness in the proposed language. In particular, because the FDA does not consider financial costs in its determinations, FDA approval does not speak to the fifth criterion of appropriateness.

The administration's HSA does not describe any relationship between FDA approval and its condition of "medically necessary or appropriate." The Cooper-Breaux bill does say that FDA approval of a treatment implies that it satisfies the bill's criteria for medial appropriateness (p 100).[4] As the Cooper-Breaux and Chafee bills are currently written, that is a correct position, because neither bill contains a criterion that addresses cost. However, if either bill were to be rewritten to address cost, FDA approval of a treatment would no longer necessarily imply that the treatment met the revised criteria.

Coverage for Investigational Treatments

The proposed language, like the language in the Cooper-Breaux and Chafee bills, and the current contracts of most insurers and HMOs, is clear in its requirement that to be medically appropriate an intervention must be noninvestigational. However, implementing this criterion raises several practical questions. Four of the most important are: What type and quality of evidence is needed to be "sufficient"? Should the investigational criterion be applied more strictly to "new" interventions than to "old" ones? If old interventions that are investigational should be treated more leniently, precisely how should they be addressed to avoid waste and harms? And, how should research on investigational interventions be funded? These issues will be the subject of a future article in this series, but first I want to treat you to a conversation with my mother.

NEXT: A Conversation with my Mother.

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4. Cooper Mr, Breaux Mr. Senate Bill 1579.

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7. Eddy D. Health system reform: Will controlling costs require rationing? JAMA 1994; (in press).

June 22, 1994

TO: Ms. Nan Hunter
Deputy Legal Counsel
Department of Health and Human Services
Washington D.C.

FROM: Linda Bergthold

RE: PREPARATION FOR THURSDAY'S MEETING ON MEDICAL NECESSITY OR APPROPRIATENESS

As you know, I have been asked by Karen Hein and other Senate Finance staff to review the options relating to the definition of medical necessity/appropriateness in proposed reform legislation. I thought it would be helpful to review some of these arguments and proposed terminology for you and your staff as well.

1. BACKGROUND ON MEDICAL NECESSITY OR APPROPRIATENESS

At the core of all clinical decision-making is the determination of what is the appropriate treatment for any given patient's condition. These decisions are generally made by physicians, sometimes in consultation with patients, and occasionally overruled by health plan administrators. What is medically necessary? Who should decide what is necessary? Who should arbitrate if there is conflict among the parties to the decision?

There are dozens of definitions of medical necessity being applied by health plans around the country today. **Medicare** has one of the most illness and injury oriented definitions (see Appendix A); **Medicaid** has different definitions in every state, some of which are surprisingly innovative (e.g. South Dakota); private plans, including HMOs, rarely publish their definitions for consumers or policymakers. Lawsuits tend to be the mechanism for bringing these definitions into the public domain.

All existing definitions of medical necessity have some elements in common: they rely on the judgment of medical practitioners and

"prevailing standards" of care; they tend to focus on curing illness rather than maintaining health; they leave final interpretation up to the administrators of the health plans. Patients and physicians are often left out of the decision making process.

In the construction of the President's plan, our working group on benefits recognized that the definition of medical necessity would be critical in shaping a national health plan. Questions such as what terms to use, how to define them, and who should define them were central to the discussion. Should the terms be defined in law? In regulation? By a national health board? By states? By each health plan? We reached some preliminary conclusions in May of 1993:

- The old terms (i.e. medically necessary) were not sufficient for the new emphasis on health maintenance and promotion; the term "medically appropriate" was selected as a more promising alternative;

- Criteria for determining medical necessity or appropriateness should be spelled out in legislation, or if not in legislation, at least be delegated to a national health board or commission;

- All parties to the decision about coverage should have a voice in the process; that is, patients should be able to determine whether coverage was beneficial from their point of view; physicians and other health practitioners should be able to judge whether a proposed treatment was effective; and health plans should be able to take into account cost effectiveness in their coverage decisions;

- Any definition we could devise should deal adequately with the issues of reproductive health, maintenance support for the disabled, parity for mental illness. This meant that decisions about reproductive health should be the responsibility of the enrollee or beneficiary; coverage for services needed by the disabled should not focus too heavily on medical care to the exclusion of other health related services; and the definition of illness should encompass mental as well as physical illness;

With these principles in mind, we proposed a definition for health plans exclusions of treatments that were not what we called at the time "medically appropriate". After the working group had disbanded, Bill Sage, Bob Valdez and I continued to work on the proposed definition,

coming up with a modification we felt was simpler and more user friendly (see Appendix B). We discussed this definition with consumers, lawyers, physicians, policymakers and health plan administrators. That definition was not introduced into any legislative proposal and remains a definition known only to a limited number of policymakers.

2. EXISTING AND PROPOSED DEFINITIONS OF MEDICAL NECESSITY/APPROPRIATENESS

What are the existing definitions of medical necessity, in law and in proposed legislation? What should the Congress do about defining these terms and what should HHS' position be on these definitions?

As Appendix A reveals, the Medicare definition is illness and injury oriented. Nevertheless, this definition has been the basis of a number of court cases and a certain amount of case law has been developed around this definition. Some would argue that we should stick with a known definition of "medical necessity"; to do otherwise would throw the legal system into a measure of chaos. Others would argue that the system will be thrown into chaos anyway, as new rules for health plans are embedded in national legislation. A completely new term, such as "medically appropriate," might avoid the lawsuits and arguments surrounding the old language.

The fact that each state defines "medical necessity" for Medicaid in a different way and thus Medicaid beneficiaries have uneven and unequal access to services, would argue for a more specific federal framework. Unfortunately, the examples presented in Appendix A demonstrate the problems with a strong set of criteria determined at the national level. Minnesota does not consider cost in its coverage determinations; South Dakota does. Problems with access to abortion only highlight the problems associated with fifty different state interpretations of medical necessity.

Currently, There are only <u>two</u> basic approaches to the definition of medical necessity in proposed legislation: 1) the term(s) are proposed but not defined (e.g. Clinton, Kennedy mark, McDermott/Wellstone, Stark, Nickles); and 2) the term is defined but changed to "medically appropriate" (e.g. Cooper/Breaux) or "medically necessary or appropriate" (e.g. Chafee) or "medically necessary and/or appropriate (Durenberger and

Kassebaum amendments).

The only definitions currently proposed in legislation spring from the Jackson Hole proposed definitions developed originally by Dr. David Eddy. Dr. Eddy's definition, as outlined in Cooper/Breaux ("medically appropriate") and Chafee ("medically necessary or appropriate") has been repudiated by Eddy for a number of reasons (see Eddy's memo in Appendix C). Without any way to bring cost considerations into the determinations of medical necessity, Eddy believes that any other definition would cause more harm than good. Furthermore, Eddy sees no important distinctions between the terms "appropriate" and "necessary" and points out that joining the terms with the conjunction "and, absent any definition of "appropriate", would open health plans to a variety of interpretations, most of which would drive costs upward. Eddy concludes that unless his complete definition of "medically appropriate" is adopted, it would be better policy if no definition were defined in legislation, leaving the issue to a National Health Board of experts.

Because this issue is so complex and has a myriad of unintended consequences for the delivery of health care, I have made the following personal recommendations to Karen Hein and the Senate Finance staff. The latest documents I have seen follow these guidelines:

1.) Legislation should include a term such as "medically appropriate" (or "medically necessary or appropriate") by which plans can make decisions about including or excluding specific treatments;

2.) A definition of this term, with criteria by which it can be applied, by the National Health Board or in report language, not in legislation;

3.) Implementation and interpretation of this term by health plans;

4.) A process developed by the NHB for resolving disputes about coverage at the health plan level.

Given that Senators Durenberger, Chafee and Kassebaum have all introduced amendments based on the existing Cooper/Eddy language, it may be necessary to develop an alternative recommendation as a basis for

contrast. If a definition must be proposed, I would recommend that you consider our adaptation of the definition proposed originally by the working group (Appendix B). It differs from the Eddy language as displayed in Cooper and Chafee in the following ways:

1) Our proposed definition is simpler in language and thus easier to understand;

2) It has been reviewed by lawyers, physicians, plan administrators, women's groups and the disability advocacy community; pediatricians?

2) It brings the patient and the physician explicitly into the decision making process;

3) It allows health plans to consider cost-benefit tradeoffs in a relatively non-threatening way (i.e. South Dakota has used this criterion for its Medicaid program.

TALKING POINTS ON MEDICAL NECESSITY

- In any benefit package, coverage is provided for items and services that are deemed medically necessary or appropriate. These **decisions are best left up to the physician and patient**, working together to select the best care. Defining this in statute would be perceived as an infringement on the practice of medicine and would likely meet with strong opposition.

- We must not define medical necessity in terms that will fix in stone the medical model which we are trying to move our system away from. Health care today, and in the future, is about **much more than the treatment of medical conditions.** Three key dimensions of health care are not captured by the language for medical necessity being proposed:

  - **Health promotion and disease prevention** - medical care goes beyond treatment of diseases and injuries. Preventive services which must be covered include risk assessment, tests for the monitoring of disease conditions, health promotion and patient education, training in self care and the management of chronic diseases.

  - **Functioning** is an essential dimension of health care. This goes beyond ability to perform activities of daily living or ability to work, which are criteria used by SSI and have been shown to discriminate against children. Health care must maximize functioning.

  - **Patient preference** - the choice of care management goes beyond what is clinically beneficial and must incorporate patient preferences and cultural acceptability.

- Defining medical necessity in statute is **particularly problematic for children's health care** as the criteria used are so different from adults. A recent and vivid example is the 1990 Zebley decision that showed that SSI was inappropriately using adult criteria to judge disability in children. Interventions for children are particularly important as they can dramatically alter the future potential and functioning of that person.

- The benefit package must be defined in statute to create and maintain a market with a level playing field where the consumer uses comparable information about a standard benefit package to choose plans and providers. If health plans are allowed to exclude services based on varying interpretations of medical necessity that rely on medical model interpretations of health interventions, they will continue to game the system through fine print and risk avoidance.

- To ensure not only the quality of medical care, but also equity in the distribution of services, a more appropriate strategy is to build and make available the information about best practices so that physicians and patients can make better choices.

- Currently, **medical necessity is not detailed in most private health insurance.** Therefore to define it in legislation does not build on current practices in the insurance market.

- Medicine and science change over time and what is today perceived as the domains of medical necessity and reflecting best practices may not be so ten or twenty years from now. We want to preserve the innovation and adaptability of the American health care system and legislative definition of medical necessity could have unforeseen negative consequences.

- Health care interventions are not only for medical conditions as proposed. The presence of a medical condition implies the *absence* of health and therefore is only one domain of health care. Medical care and interventions also include the promotion of health and the maximizing of functioning.

- Not all health care interventions or treatment options will affect the *outcome* of care. In other words, services may affect such things as the length of illness, patient satisfaction, or the cost of care but not change the ultimate outcome Therefore, defining an item or service as medically necessary only if it affects a health *outcome* is very limiting.

- Defining an adverse change in a health outcome only in terms of biological or psychological domains does not capture the full range of medical care interventions. For example, children with learning disability may benefit from drug treatment to improve their *behavior* and therefore their learning ability. This is a change in behavioral health status, not biological or psychological. Another example, providing a wheelchair to a disabled person does not change their biology or psychology, it assists their *functioning*. Similarly, eyeglasses and hearing aids assist or maximize functioning.

- In decisions related to appropriateness for a specific patient it is important to ensure that patient preferences in care be respected. One therapy may be superior to another in terms of "clinically meaningful benefit" but be unacceptable to the patient in terms of risks, discomfort, or cultural acceptability. For example, a cancer patient may choose the less "clinically beneficial" treatment - in terms of cancer eradication - because it provides the best quality of life for the remaining weeks or months.

- Coverage decisions by health plans should be, to the extent possible, based on science. It is important however to realize that the scientific literature often includes conflicting evidence as to benefit or appropriateness, especially for new therapies. Allowing plans to use all literature or prevailing practice could mean that any single report of lack of effectiveness could be used to exclude treatments.

TALKING POINTS ON MEDICAL NECESSITY

- In any benefit package, coverage is provided for items and services that are deemed medically necessary or appropriate. These **decisions are best left up to the physician and patient**, working together to select the best care. Defining this in statute would be perceived as an infringement on the practice of medicine and would likely meet with strong opposition.

- A strategy that couples defining medical necessity/appropriateness in legislation while not defining the benefit package itself will hobble any reform efforts to move our health care system away from high cost medical care of established problems and result in health plans continuing to game the system through risk avoidance.

- We must not define medical necessity in terms that will fix in stone the medical model which we are trying to move our system away from. Health care today, and in the future, is about **much more than the treatment of medical conditions**. Three key dimensions of health care are not captured by the language for medical necessity being proposed:

  - **Health promotion and disease prevention** - medical care goes beyond treatment of diseases and injuries. Preventive services which must be covered include risk assessment, tests for the monitoring of disease conditions, health promotion and patient education, training in self care and the management of chronic diseases.

  - **Functioning** is an essential dimension of health care. This goes beyond ability to perform activities of daily living or ability to work, which are criteria used by SSI and have been shown to discriminate against children. Health care must maximize functioning.

  - **Patient preference** - the choice of care management goes beyond what is clinically beneficial and must incorporate patient preferences and cultural acceptability.

- Defining medical necessity in statute is **particularly problematic for children's health care** as the criteria used are so different from adults. A recent and vivid example is the 1990 Zebley decision that showed that SSI was inappropriately using adult criteria to judge disability in children. Interventions for children are particularly important as they can dramatically alter the future potential and functioning of that person.

- The benefit package must be defined in statute to create and maintain a market with a level playing field where the consumer uses comparable information about a standard benefit package to activate the market.

- To ensure not only the quality of medical care, but also equity in the distribution of services, a more appropriate strategy is to build and make available the information about best practices so that physicians and patients can make better choices.

- Currently, **medical necessity is not detailed in most private health insurance.** Therefore to define it in legislation does not build on current practices in the insurance market.

- Medicine and science change over time and what is today perceived as the domains of medical necessity and reflecting best practices may not be so ten or twenty years from now. We want to preserve the innovation and adaptability of the American health care system and legislative definition of medical necessity could have unforeseen negative consequences.

MORE SPECIFIC FOR YOU JENNIFER:

- Health care interventions are not only for medical conditions as proposed. The presence of a medical condition implies the *absence* of health and therefore is only one domain of health care. Medical care and interventions also include the promotion of health and the maximizing of functioning.

- Not all health care interventions or treatment options will affect the *outcome* of care. In other words, services may affect such things as the length of illness, patient satisfaction, or the cost of care but not change the ultimate outcome. Therefore, defining an item or service as medically necessary only if it affects a health *outcome* is very limiting.

- Defining an adverse change in a health outcome only in terms of biological or psychological domains does not capture the full range of medical care interventions. For example, children with learning disability may benefit from drug treatment to improve their *behavior* and therefore their learning ability. This is a change in behavioral health status, not biological or psychological. Another example, providing a wheelchair to a disabled person does not change their biology or psychology, it assists their *functioning*. Similarly, eyeglasses and hearing aids assist or maximize functioning.

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- Coverage decisions by health plans should be, to the extent possible, based on science. It is important however to realize that the scientific literature often includes conflicting evidence as to benefit or appropriateness, especially for new therapies. Allowing plans to use all literature or prevailing practice could mean that any single report of lack of effectiveness could be used to exclude treatments.

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9-696-8425

AMENDMENT NO. ____ Calendar No. ____

Purpose: To provide criteria for the determination of medical necessity and appropriateness by health plans and not by the National Health Board.

IN THE SENATE OF THE UNITED STATES—103d Cong., 2d Sess.

S. 1779

To ensure individual and family security through health care coverage for all Americans in a manner that contains the rate of growth in health care costs and promotes responsible health insurance practices, to promote choice in health care, and to ensure and protect the health care of all Americans.

Referred to the Committee on _____
and ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT intended to be proposed by [redacted]

Viz:

Strike subsection (a) of section 1141 and insert the following:

(a) MEDICAL NECESSITY ~~AND APPROPRIATENESS~~.—

(1) IN GENERAL.—The comprehensive benefit package shall provide coverage for health care intervention that the health plan determines is medically necessary and appropriate.

(2) CRITERIA FOR DETERMINATION OF MEDICAL NECESSITY ~~AND APPROPRIATENESS~~.—

(A) IN GENERAL.—In making a determination of medical necessity or appropriateness and subject to the succeeding provisions of this paragraph, for purposes of this title, health care intervention (as defined in subparagraph (F)(i)) shall be considered to be "medically necessary ~~and appropriate~~" if the following criteria are met:

(i) TREATMENT OR DIAGNOSIS OF MEDICAL CONDITION.—

(I) IN GENERAL.—The health care intervention is for a medical condition.

(II) MEDICAL CONDITION DEFINED.—The term "medial condition" means a disease, illness, injury, genetic defect, or biological or psychological condition or status for which health care intervention is indicated to improve, maintain, restore, or stabilize a health outcome (as defined in subparagraph (F)(ii)) or which, in the absence of such intervention, could

lead to an adverse change in ~~a~~ health outcome.

(III) ADVERSE CHANGE IN HEALTH OUTCOME DEFINED.—In subclause (II), an adverse change in a health outcome occurs if there is a biological or psychological decremental change in a health status.

(ii) SAFE AND EFFECTIVE.—An item is safe and effective if there is sufficient evidence to demonstrate that such item can reasonably be expected to produce the intended health outcome or provide the intended health information.

(iii) MEDICALLY APPROPRIATE FOR THE SPECIFIC PATIENT.—An item or service is medically appropriate for a specific patient if, with respect to that patient's medical condition, the item or service can reasonably be expected to provide a clinically meaningful benefit and such item or service is furnished in a setting commensurate with the patient's medical needs.

(B) PRESUMPTIONS.—

(i) A drug or biologic which is approved for marketing by the Food and Drug Administration is deemed to be safe and effective if such drug or biologic is furnished for treatment of a medically accepted indication (as defined in section 1122(a)(1)).

(ii) A medical device that has been cleared for marketing by the Food and Drug Administration is deemed safe and effective when used for the conditions prescribed, recommended, or suggested in the labeling of the device.

(iii) An item or service furnished to a patient consistent with a practice guideline developed by the Agency for Health Care Policy and Research under section 912(a) of the Public Health Service Act or certified under section 912(g) of the Public Health Service Act is deemed to be safe and effective, but the omission of an item or procedure from a practice guideline does not give rise to a presumption that an item or procedure is not safe and effective.

(C) COVERAGE OF INVESTIGATIONAL TREATMENTS IN APPROVED RESEARCH TRIALS.—

(i) IN GENERAL.—Coverage of the patient care costs (as defined in clause (iii)) associated with the delivery of investigational treatments (as defined in clause (ii)) are considered to be medically necessary ~~and appropriate~~ only if the treatment for the patient is part of an approved research trial (as defined in clause (iv)).

(ii) INVESTIGATIONAL TREATMENT DEFINED.—In clause (i), the term "investigational treatment" means health care intervention for which there is not sufficient evidence to establish that such intervention is safe and effective as determined under subparagraph (A)(ii).

(iii) PATIENT CARE COSTS DEFINED.—In clause (i), the term "patient care costs" means the cost of health services required to provide treatment according to the design of the trial, except those costs normally paid for by other funding sources (as defined by the Secretary), such

as the cost of an investigational drug, the costs of any nonhealth services that might be required for a person to receive the treatment, or the costs of managing the research. Items or services subject to this exception may be covered in addition to patient care at the discretion of the health plan.

(iv) APPROVED RESEARCH TRIAL DEFINED.—In clause (i), the term "approved research trial" means a trial—

(I) conducted for the primary purpose of determining whether or not a health care intervention is safe, effective, or having any other character of a health care intervention which must be demonstrated in order for the health care intervention to be medically necessary and appropriate, and

(II) approved by the Secretary.

A trial is deemed to be approved under subclause (II) if such trial is approved by the National Institutes of Health, the Food and Drug Administration (through an investigational new drug exemption), the De-

pursuant to 21 U.S.C. § 355 or an investigational device exemption pursuant to 21 U.S.C. § 360j(g))

partment of Veterans Affairs, the Department of Defense, or by a qualified non-governmental research entity (as identified in guidelines issued by one or more of the National Institutes of Health).

(D) COVERAGE DECISIONS.—

(i) IN GENERAL.—Each plan shall provide for coverage of all items and services within the comprehensive benefit package. A plan at its discretion may, but is not required to, exclude items or services pursuant to this subparagraph.

→ can exclude if any of these conditions not met?

(ii) DETERMINATION.—In determining whether an item or service is medically necessary and appropriate, as defined in subsection (a), a health plan shall consider—

(I) any presumptions established pursuant to section 1141(a)(2)(B);

(II) any determinations by the Food and Drug Administration with respect to its safety and effectiveness;

(III) any practice guidelines that have been developed or certified under

section 912 of the Public Health Service Act;

(IV) published peer-reviewed medical literature;

(V) opinions of medical specialty groups; and

(VI) evidence of general acceptance in the medical community.

(iii) TREATMENT GUIDELINES OR UTILIZATION PROTOCOLS.—In the event a health plan has established a treatment guideline or utilization protocol, or has made a determination of general applicability that a particular item or service is not available to the plan's enrollees as part of the comprehensive benefits package, the health plan shall provide a copy of the guideline, protocol, or determination and a written statement of the basis thereof—

(I) at least 60 days prior to its effective date to the certifying authority and to each affected provider with which the plan has a contract; and

(II) upon request, within 30 days to any interested party.

(iv) REQUIREMENTS.—Any treatment guideline, utilization protocol, or determination of general applicability used by a plan in implementing this section—

(I) shall be revised as soon as practicable after new evidence of the type described in subsection (a) becomes available, but in no event shall a plan's guideline, utilization protocol, or determination remain in effect for more than 1 year after the development of new evidence without reevaluation and republication pursuant to subsection (b) of the determination, guideline, or protocol and a written statement of the basis thereof, and

(II) copies of all treatment guidelines, utilization protocols, and determinations of general applicability, and a description of the process for providers to comment on such guidelines, protocols and determinations and revisions thereto, shall be supplied to each provider contracting with the plan to be a participating provider.

Prior to implementing any guideline, protocol, or determination pursuant to this section, the health plan shall give due consideration to comments the plan may receive from providers and other interested persons.

(E) HEALTH CARE INTERVENTION AND HEALTH OUTCOME DEFINED.—As used in this paragraph:

(i) IN GENERAL.—The term "health care intervention" means any activity undertaken, with respect to a specific indication, to diagnose, improve, maintain, restore, or stabilize a health outcome or to prevent or mitigate an adverse change in a health outcome.

(ii) HEALTH OUTCOME.—The term "health outcome" means an outcome that affects the length or quality of an enrollee's life. Improved quality of life includes ability to perform activities of daily living, ability to work, relief from discomfort or pain, alleviation of fatigue, and improved cognitive, social, or emotional functioning and well-being.

Strike sections 1151 and 1154 and insert the following:

SEC. 1154. ESTABLISHMENT OF PRACTICE GUIDELINE.

(a) IN GENERAL.—The Board may recommend that the Agency for Health Care Policy and Research undertake the development of a practice guideline or a clinical list if the Board determines that health plans need guidance for determination of coverage decisions for an item or service.

(b) PETITION FOR GUIDELINE.—Health plans, providers, or citizens may petition the Agency for Health Care Policy and Research to request the development of a guideline. The Agency for Health Care Policy and Research must consider all such requests in determining its priorities.

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June 7, 1994

Senator Edward M. Kennedy
United States Senate
Committee on Labor and Human Resources
Health Policy Office
527 Hart Office Building
Washington, DC 20510

Sent Via Facsimile: 202-224-3533, Attn: Mary Beth Fiske, Robert St. Peter

Dear Senator Kennedy:

I am writing to you to express my concern that your committee may eliminate the potential of offering the American people a defined benefit package, unwisely vest unjust decision making authority in the hands health care plans to determine the real nature of the services that will be provided, and remove additional federal safeguards while imposing additional barriers for patients and consumers. I am a pediatrician, an Associate Professor of Pediatrics and Public Health at UCLA, and a consultant to the Health Sciences program at the RAND Corporation, where I am working on developing measures of quality and appropriateness of health care services for children. I also serve as Co-chair of the Ambulatory Pediatrics Committee on Serving the Underserved.

I was informed that Senator Durenberger has proposed amendments to your health care reform bill that would attempt to define medical necessity, eliminate the role of the National Health Board and potentially lead the way to the elimination of a guaranteed benefit package. I have had the opportunity to review the language in these proposed amendments and want to voice my strong opposition to them as they are proposed. As you know, when I testified before your committee in November of 1993, I suggested that a definition of medical necessity was advisable as part of a child standard of coverage. I argued that the unique health needs of children warranted special consideration in the provision of a comprehensive benefit package with clear language that defined and delineated medical necessity. Because restrictive definitions of medical necessity have been used by health plans to inappropriately withhold treatments for children I suggested at that time, and still believe, that medical necessity for children must be judged using different criteria than is routinely used for determining medical necessity for adults.

From my reading of the Durenberger amendments there are three components. First, the amendments limit the comprehensive benefit package to those treatments or diagnostic procedures that the health plan determines are medically necessary or appropriate.

Second, these amendments attempt to provide criteria to judge medical necessity or appropriateness. Lastly, they would modify the authority of the National Health Board by eliminating its role in issuing regulation that would define medical necessity and appropriate care.

These provisions would basically place health care plans in the role making decisions regarding which diagnostic procedures and treatment services to provide, eliminate the important federal regulatory role in assuring that particularly vulnerable population are fairly treated by the plans, and place needless and virtually insurmountable barriers in the path of consumers who might choose to challenge the exclusion of a service. As a pediatrician I am especially concerned for two reasons. First, health care plans have historically under-financed or ignored the types of care that are most important for children. The problem is especially acute for children with chronic or disabling conditions, or other vulnerable children such as those children who are in foster care or other circumstances that place them at risk for severe yet avoidable health problems. As my colleagues at RAND and UCLA and I have recently demonstrated, many managed care plans are not even able to deliver the most basic preventive services -- immunizations -- to infants and young children in inner city Los Angeles. Unless Congress unequivocally establishes that all health plans are responsible for providing their members with a basic level of coverage, I see no reason that these troubling practices will change.

Second, the current state of knowledge and the art (or artifice) of determining medical necessity is very underdeveloped. This is particularly true for children, where there has been much less work done on the development of practice guidelines and appropriateness criteria than for adult males, and where the development of such standards of care face unique methodological issues, that while surmountable, will take some time to solve. Allowing health plans to make such determinations on their own, without clear scientific evidence to rule a treatment in or out, and with economic pressures to eliminate services, place these plans in a supremely powerful role vis a vis patients, with overwhelming economic incentives that will clearly influence determinations. Moreover, since these amendments shift the burden of proof in the administrative and judicial process to the patient, the patient is put in the untenable role of having to prove that a procedure is necessary without professional consensus or a standard to rely upon.

As I stated earlier, I firmly believe that language defining medical necessary services is important, but only in the context of a guaranteed benefit package, and regulatory body such as the National Health Board that can objectively evaluate the application of such criteria and their appropriateness. Medical necessity language without a guaranteed benefit package and objective federal mechanism for modifying what services are included is not only insufficient, but as proposed by Senator Durenberger is frankly dangerous, especially to women and children. Vesting so much power, and authority in health plans would not be in the best interest of many Americans and especially our children. Congress has the responsibility of assuring that if coverage is to be denied that these decisions not be made on bottom line concerns about the return on investments for the health plan, but

with adequate consideration about the health and well being of each individual patient. In this regard federal guidance and oversight is essential.

Sincerely,

Neal Halfon, MD, MPH
Associate Professor of Pediatrics
and Public Health

NH/svg
lken0607.doc

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June 6, 1994

Senator Edward M. Kennedy
United States Senate
Committee on Labor and Human Resources
Health Policy Office
527 Hart Office Building
Washington, DC 20510

BY FAX TO: (202) 224-3533
Attn: Mary Beth Fiske

Dear Senator Kennedy:

I am writing as Co-Chair of the Committee on Access to Justice in Health Care Reform of the Society of American Law Teachers (SALT). With almost 800 members at over 140 law schools,, SALT is the largest individual membership organization of people who teach in American law schools. Since its inception in 1974, SALT has addressed issues of access to justice and discrimination in many areas of American life. In October 1993 the SALT Board of Governors authorized the creation of a special committee to work on access to justice issues within health care reform, and we are pleased to have enlisted the participation of many of the leading American law professors who analyze the organization and delivery of health care services.

I was informed today of Senator Durenberger's proposed amendments to your health care reform bill regarding the definition of medical necessity and the role of the National Health Board. I understand that this amendment may be considered as early as tomorrow, and I am writing immediately to express my strong opposition to this amendment. I will be glad to provide additional comments when I have had an opportunity to consult the full SALT Committee.

The Durenberger amendment has three major provisions. First, it limits the comprehensive benefit package to a treatment or diagnostic procedure that "the health plan determines is medically necessary or appropriate." Proposed 1141(a)(1). Second, it attempts to provide criteria to resolve "disputes concerning a determination of medical necessity or appropriateness." A treatment or procedure "shall be considered to be 'medically necessary or appropriate' if the following criteria are met," including "sufficient evidence on which to base conclusions about the existence and magnitude of the change in health outcome resulting from the treatment [or procedure] compared with the best available alternative," and evidence that "demonstrate[s] that the

treatment . . . can reasonably be expected to produce the intended health result . . . and provides a clinically meaningful benefit with respect to safety and effectiveness in comparison to other available alternatives . . . ." Proposed 1141(a)(2)(A),(ii), (iii). "Investigational" treatments generally excluded from coverage (except in approved research trials) are defined as "a treatment for which there is not sufficient evidence to determine the health outcome of the treatment compared with the best available alternative treatment (or with no treatment if there is no alternative treatment). Proposed 1141(a)(2)(C). Evidence to be used in making coverage decisions "under any arbitration process" appears to be limited to published peer-review literature, opinions of medical specialty groups "and other medical experts," and "evidence of general acceptance by the medical community." Proposed 1141(a)(2)(E). The Durenberger amendment would also eliminate the authority of the National Health Board to issue regulations defining what services are excluded from coverage on the grounds of not being medically necessary or appropriate.

The effect of these provisions is to grant health plans vast discretion to exclude treatments and diagnostic procedures from coverage, and to place almost insurmountable obstacles to consumers attempting to challenge such exclusions. This is particularly true for treatments focused on women and children, for whom systematic evidence is even less available than for adult men. Given the early and undeveloped state of knowledge about medical necessity and appropriateness for all patients, the fluidity and lack of consensus in the managed care industry, and new financial incentives, granting health plans such expansive power is exceedingly unwise and even dangerous. To take this radical step in American health law in the rush of a legislative mark-up, without hearings and serious public consideration, is to run severe risks in terms of patient welfare and political reaction.

Even without health care reform, the increasing efforts by health plans to influence the care of individual patients are diverse, changing, and the subject of vigorous debate. As the 1989 Institute of Medicine (IOM) study of utilization management put it, "we find a series of working hypotheses and partial solutions that are continually revised, discarded, and even reinvented as changes occur in medical technology, social values, economic conditions, and other circumstances."[1] The IOM utilization management study also found that "[s]ystematic evidence about the impact of utilization management methods on the quality of care and on

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[1] Institute of Medicine, Controlling Costs and Changing Patient Care? The Role of Utilization Management (Bradford H. Gray & Marilyn J. Field, eds., 1989)[hereinafter cited as "IOM/Utilization"] at 1.

patient and provider costs is virtually nonexistent."[2] Given the wide variety of criteria, incentives, training, supervision, and implementation methodologies found, the Institute of Medicine recommended, inter alia, that utilization management criteria (including those used by hospitals and HMOs) should be available for outside scrutiny by physicians, purchasers, and patients, and that a system for patients and physicians to appeal utilization management decisions "is an essential protection for patients."[3]

None of this is to say that guidelines, criteria of necessity and appropriateness, and other devices may not be useful in different contexts and for different purposes. It is to say that guidelines and criteria are currently being developed by a wide range of entities (e.g. professional societies, hospitals, HMOs, insurance companies) for many different purposes, including payment policy and utilization management, and that there is little consensus on methodology or criteria for guideline evaluation. In 1990, an Institute of Medicine study committee on clinical practice guidelines found that "no explicit method was available for assessing existing or emerging practice guidelines . . . . nothing existed to judge the quality, reliability, and validity of the content of the guideline itself."[4] Moreover, given this lack of professional and industry consensus, the impact of financial motivation can be substantial. As Dr. Robert H. Brook, a leading researcher on medical necessity and appropriateness points out, varying economic perspectives could influence the definition of "appropriateness" of, for example, three major surgical procedures in a range from 88 to 36 percent of current utilization.[5]

Against this background of transition and uncertainty, two legislative issues are of critical importance: (1) the allocation of the burden of proof in the administrative and judicial process, and (2) incorporation of patient interests and perspectives into the guidelines or criteria themselves. Regarding the first, the Kennedy bill properly places the burden of justification on those seeking to deny services, section 5204(d)(1). If the claimant has the burden of proving that a clinical practice guideline or necessity/appropriateness exclusion is "invalid," that may well be impossible, because of the absence of professional consensus concerning standards for validity, and the possibly large costs

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[2] IOM/Utilization, supra note 1, at 4.

[3] IOM/Utilization, supra note 1, at 6 (emphasis supplied).

[4] Institute of Medicine, Guidelines for Clinical Practice (Marilyn J. Field and Kathleen N. Lohr, eds., 1992)[hereinafter cited as "IOM/Guidelines"] at 346.

[5] Robert H. Brook, "Practice Guidelines and Practicing Medicine: Are They Compatible?", 262 J.A.M.A. 3027, 3029 (1988).

involved in trying to present such proof. Placing the burden on the plan to prove the guideline or exclusion "valid" or at least "not invalid" is defensible on several grounds. First, the health plan has far greater resources to conduct research and mobilize medical expertise. Second, the plan will of course be knowledgeable about its own process of guideline or criteria development. Third, placing the burden on the plan would have the beneficial effect of providing plans with an incentive to be careful and to use the best available methods in their development of guidelines and coverage criteria.

Regarding the second, the IOM 1992 Guidelines Report recommends as "desirable attributes" of medical review criteria (guidelines when used by management or third parties) the following (among others): patient responsiveness ("review criteria should specifically identify a role for patient preferences or ensure that the process for using them allows some consideration of patient preferences"); readability ("review criteria should be presented in language and formats that can be read and understood by nonphysician reviewers, practitioners, and patient/consumers"); and appeals criteria ("criteria should provide explicit guidance about the considerations to be taken into account when adverse decisions are appealed by professionals or patients").[6] The Report also calls for development of "general guidelines on patient information and informed consent" through "a more inclusive development process involving . . . more representation of health care purchasers and third-party payers, consumers and patients, and the legal profession."[7] The National Health Board or other national body should be required to develop policies on these matters within a set period (e.g. two years), which would be binding on the administrative review (and plan certification) process, or report to Congress on why such a mandate could not be achieved and what legislative changes should be enacted as a consequence.

The Durenberger amendment undermines the Kennedy bill's allocation of the burden of proof, ignores the need for consumer-responsive criteria of necessity/appropriateness or "medical review," and eliminates the national administrative authority needed to develop such consumer responsiveness and public accountability. Although the Durenberger amendment does not amend section 5204(d)(1) in formal terms, it casts doubt on its meaning by (i) granting health plans the power to "determine" what is medically necessary or appropriate, (ii) declaring that treatments and procedures shall be considered medically necessary or appropriate if certain criteria are met (thereby suggesting that the burden of persuasion or justification is on those seeking coverage), and (iii) specifying certain types and amounts of

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[6] IOM/Guidelines, supra note 4, at 9.

[7] Id. at 152; see also id. at 204, 217-219.

evidence needed to satisfy (ii). Moreover, the Durenberger amendment presumes that criteria of necessity and appropriateness and their application are matters of hard science, ignoring the judgmental and policy issues that most experts in the field acknowledge as pervasive, and unwisely eliminating the regulatory powers of the National Health Board.

Finally, the Durenberger amendment is technically problematic. Terms such as "health outcome," "decremental change in a health status," "magnitude of the change in health outcome," and "other medical experts," while presumably intended to structure and rationalize dispute resolution, are actually more likely to increase uncertainty and litigation.

The development of a process to define and implement concepts of medical necessity and appropriateness is one of the great political, professional, scientific, and human challenges of our time. It should not be done hurriedly, without hearings, in a legislative mark-up. It should be given the respect that its complexity and importance deserve.

Sincerely,

Rand E. Rosenblatt
Professor of Law
tel: (609) 225-6379
FAX: (609) 225-6516

Potential Standards for Medical Necessity
for the National Health Board

1. Criteria similar to Cooper/Chafee

   - treatment of medical conditions
   - not investigational
   - effective and safe
   - consistent with practice guideline

1a: Limits of Cooper/Chaffee

   - preventive services - risk assessment, tests for monitoring/surveillance of disease conditions, health promotion;
   - patient education, etc to reduce risk behaviors, training in self care and the management of chronic diseases, etc...;
   - adverse change in health outcome: need to include quality of life, functional status, cognitive, and behavioral outcomes, not just biological or psychological decrements;
   - relationship to developmental needs, promotion of optimal outcomes, and link to different appropriateness at different ages

2. Explicitly addressing the role of the physician in decisions about medical necessity/appropriateness

   - physician role in facilitating and promoting patient choice through:

     - disclosure of therapeutic options (duty to inform) with information on risks and benefits
     - appropriate explanations which are understandable to patient
     - working through the decisionmaking process
     - seeking informed consent in ways that are effective and culturally competent, especially for populations that have been up to now excluded from the system

   - respect of patient rights including autonomy, patient privacy and confidentiality, and right to refuse unwanted treatments

   - physician non discrimination in clinical judgment as to decisions on medical necessity

   - physician responsibility to not have own moral/religious views interfere with decisions

   - physician role as patient advocate

3. Explicitly addressing the role of the patient in decisions about medical necessity/appropriateness

   - seeking and informing themselves about options
   - informed decisionmaking about health plans and providers
   - patient rights if disagreements occur as to medical necessity/appropriateness
   - speak to the role of family and other loved ones in decisions about treatment

4. Decisions must result in equitable and appropriate access to services for all with safeguards for previously underserved groups

5. Role of surrogates/advocates in decisions

6. Role and limits on health plans in such decisions

7. Relationship of rights and remedies and consumer protection provisions in HSA to decisions of medical necessity/appropriateness

8. Confidentiality

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF THE ASSISTANT SECRETARY FOR LEGISLATION
HEALTH LEGISLATION
WASHINGTON, D.C. 20201

PHONE: (202) 690-7450 FAX: (202) 690-8425

TO: Jennifer Klein FROM: Bridgett Taylor

NAME: NAME:

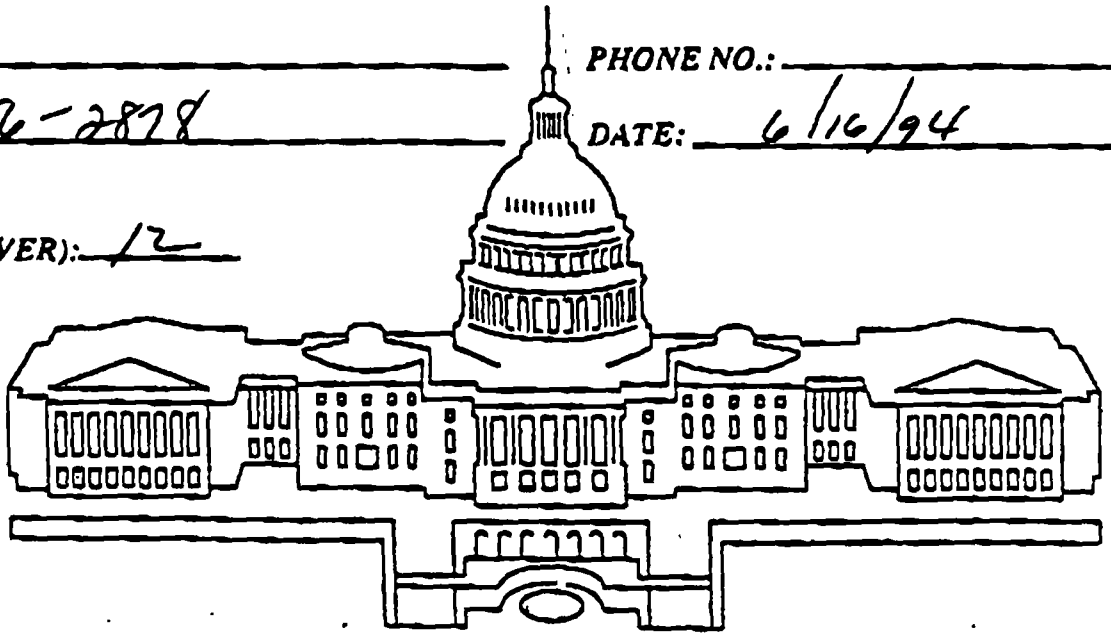
OFFICE: OFFICE:

ROOM NO.: ROOM NO.:

PHONE NO.: PHONE NO.:

FAX NO.: 456-2878 DATE: 6/16/94

TOTAL PAGES
(INCLUDING COVER): 12



REMARKS:

The Durenberger amendment to SEC. Please call Debbie Chang - 224-3612

Thanks Bridgett

4-696-8425 / 456-2878 Jennifer Keller

AMENDMENT NO. ____ Calendar No. ____

Purpose: To provide criteria for the determination of medical necessity and appropriateness by health plans and not by the National Health Board.

IN THE SENATE OF THE UNITED STATES—103d Cong., 2d Sess.

S. 1779

To ensure individual and family security through health care coverage for all Americans in a manner that contains the rate of growth in health care costs and promotes responsible health insurance practices, to promote choice in health care, and to ensure and protect the health care of all Americans.

Referred to the Committee on _____
and ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT intended to be proposed by [redacted]

Viz:

Strike subsection (a) of section 1141 and insert the following:

(a) MEDICAL NECESSITY AND APPROPRIATENESS.—

(1) IN GENERAL.—The comprehensive benefit package shall provide coverage for health care intervention that the health plan determines is medically necessary and appropriate.

(2) CRITERIA FOR DETERMINATION OF MEDICAL NECESSITY AND APPROPRIATENESS.—

(A) IN GENERAL.—In making a determination of medical necessity or appropriateness and subject to the succeeding provisions of this paragraph, for purposes of this title, health care intervention (as defined in subparagraph (F)(i)) shall be considered to be "medically necessary and appropriate" if the following criteria are met:

(i) TREATMENT OR DIAGNOSIS OF MEDICAL CONDITION.—

(I) IN GENERAL.—The health care intervention is for a medical condition.

(II) MEDICAL CONDITION DEFINED.—The term "medial condition" means a disease, illness, injury, genetic defect, or biological or psychological condition or status for which health care intervention is indicated to improve, maintain, restore, or stabilize a health outcome (as defined in subparagraph (F)(ii)) or which, in the absence of such intervention, could

lead to an adverse change in ~~a~~ health outcome.

(III) ADVERSE CHANGE IN HEALTH OUTCOME DEFINED.—In subclause (II), an adverse change in a health outcome occurs if there is a biological or psychological decremental change in a health status.

(ii) SAFE AND EFFECTIVE.—An item is safe and effective if there is sufficient evidence to demonstrate that such item can reasonably be expected to produce the intended health outcome or provide the intended health information.

(iii) MEDICALLY APPROPRIATE FOR THE SPECIFIC PATIENT.—An item or service is medically appropriate for a specific patient if, with respect to that patient's medical condition, the item or service can reasonably be expected to provide a clinically meaningful benefit and such item or service is furnished in a setting commensurate with the patient's medical needs.

(B) PRESUMPTIONS.—

(i) A drug or biologic which is approved for marketing by the Food and Drug Administration is deemed to be safe and effective if such drug or biologic is furnished for treatment of a medically accepted indication (as defined in section 1122(a)(1)).

(ii) A medical device that has been cleared for marketing by the Food and Drug Administration is deemed safe and effective when used for the conditions prescribed, recommended, or suggested in the labeling of the device.

(iii) An item or service furnished to a patient consistent with a practice guideline developed by the Agency for Health Care Policy and Research under section 912(a) of the Public Health Service Act or certified under section 912(g) of the Public Health Service Act is deemed to be safe and effective, but the omission of an item or procedure from a practice guideline does not give rise to a presumption that an item or procedure is not safe and effective.

(C) COVERAGE OF INVESTIGATIONAL TREATMENTS IN APPROVED RESEARCH TRIALS.—

(i) IN GENERAL.—Coverage of the patient care costs (as defined in clause (iii)) associated with the delivery of investigational treatments (as defined in clause (ii)) are considered to be medically necessary and appropriate only if the treatment for the patient is part of an approved research trial (as defined in clause (iv)).

(ii) INVESTIGATIONAL TREATMENT DEFINED.—In clause (i), the term "investigational treatment" means health care intervention for which there is not sufficient evidence to establish that such intervention is safe and effective as determined under subparagraph (A)(ii).

(iii) PATIENT CARE COSTS DEFINED.—In clause (i), the term "patient care costs" means the cost of health services required to provide treatment according to the design of the trial, except those costs normally paid for by other funding sources (as defined by the Secretary), such

as the cost of an investigational drug, the costs of any nonhealth services that might be required for a person to receive the treatment, or the costs of managing the research. Items or services subject to this exception may be covered in addition to patient care at the discretion of the health plan.

(iv) APPROVED RESEARCH TRIAL DEFINED.—In clause (i), the term "approved research trial" means a trial—

(I) conducted for the primary purpose of determining whether or not a health care intervention is safe, effective, or having any other character of a health care intervention which must be demonstrated in order for the health care intervention to be medically necessary and appropriate, and

(II) approved by the Secretary.

A trial is deemed to be approved under subclause (II) if such trial is approved by the National Institutes of Health, the Food and Drug Administration (through an investigational new drug exemption), the De-

pursuant to 21 U.S.C. §355 or an investigational device exemption pursuant to 21 U.S.C. §360j(g))

partment of Veterans Affairs, the Department of Defense, or by a qualified non-governmental research entity (as identified in guidelines issued by one or more of the National Institutes of Health).

(D) COVERAGE DECISIONS.—

(i) IN GENERAL.—Each plan shall provide for coverage of all items and services within the comprehensive benefit package. A plan at its discretion may, but is not required to, exclude items or services pursuant to this subparagraph.

(ii) DETERMINATION.—In determining whether an item or service is medically necessary and appropriate, as defined in subsection (a), a health plan shall consider—

(I) any presumptions established pursuant to section 1141(a)(2)(B);

(II) any determinations by the Food and Drug Administration with respect to its safety and effectiveness;

(III) any practice guidelines that have been developed or certified under

section 912 of the Public Health Service Act;

(IV) published peer-reviewed medical literature;

(V) opinions of medical specialty groups; and

(VI) evidence of general acceptance in the medical community.

(iii) TREATMENT GUIDELINES OR UTILIZATION PROTOCOLS.—In the event a health plan has established a treatment guideline or utilization protocol, or has made a determination of general applicability that a particular item or service is not available to the plan's enrollees as part of the comprehensive benefits package, the health plan shall provide a copy of the guideline, protocol, or determination and a written statement of the basis thereof—

(I) at least 60 days prior to its effective date to the certifying authority and to each affected provider with which the plan has a contract; and

(II) upon request, within 30 days to any interested party.

(iv) REQUIREMENTS.—Any treatment guideline, utilization protocol, or determination of general applicability used by a plan in implementing this section—

(I) shall be revised as soon as practicable after new evidence of the type described in subsection (a) becomes available, but in no event shall a plan's guideline, utilization protocol, or determination remain in effect for more than 1 year after the development of new evidence without reevaluation and republication pursuant to subsection (b) of the determination, guideline, or protocol and a written statement of the basis thereof, and

(II) copies of all treatment guidelines, utilization protocols, and determinations of general applicability, and a description of the process for providers to comment on such guidelines, protocols and determinations and revisions thereto, shall be supplied to each provider contracting with the plan to be a participating provider.

Prior to implementing any guideline, protocol, or determination pursuant to this section, the health plan shall give due consideration to comments the plan may receive from providers and other interested persons.

(E) HEALTH CARE INTERVENTION AND HEALTH OUTCOME DEFINED.—As used in this paragraph:

(i) IN GENERAL.—The term "health care intervention" means any activity undertaken, with respect to a specific indication, to diagnose, improve, maintain, restore, or stabilize a health outcome or to prevent or mitigate an adverse change in a health outcome.

(ii) HEALTH OUTCOME.—The term "health outcome" means an outcome that affects the length or quality of an enrollee's life. Improved quality of life includes ability to perform activities of daily living, ability to work, relief from discomfort or pain, alleviation of fatigue, and improved cognitive, social, or emotional functioning and well-being.

Strike sections 1151 and 1154 and insert the following:

SEC. 1154. ESTABLISHMENT OF PRACTICE GUIDELINE.

(a) IN GENERAL.—The Board may recommend that the Agency for Health Care Policy and Research undertake the development of a practice guideline or a clinical list if the Board determines that health plans need guidance for determination of coverage decisions for an item or service.

(b) PETITION FOR GUIDELINE.—Health plans, providers, or citizens may petition the Agency for Health Care Policy and Research to request the development of a guideline. The Agency for Health Care Policy and Research must consider all such requests in determining its priorities.

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8. Confidentiality

U.S. Dept. of Health and Human Services
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United States General Accounting Office

GAO

Testimony

Before the Subcommittee on Regulation, Business Opportunities, and Technology, Committee on Small Business, House of Representatives

For Release on Delivery
Expected at
9:30 a.m., EST
Tuesday
March 29, 1994

MEDICARE PART B

Inconsistent Denial Rates for Medical Necessity Across Six Carriers

Statement of Eleanor Chelimsky
Assistant Comptroller General
Program Evaluation and Methodology Division

GAO/T-PEMD-94-17

Mr. Chairman and Members of the Subcommittee:

It is a pleasure to be here to share with you the results of our ongoing work on the Medicare Part B claims processing system. As you requested, in our testimony today, we will present information on claims processed by six carriers that were denied for lack of medical necessity. To develop this information, we analyzed data provided to us by the Health Care Financing Administration (HCFA).

Before turning to the results of our work, let me briefly discuss the program and the process by which carriers determine medical necessity.

The Medicare program, authorized under title XVIII of the Social Security Act, is a nationwide entitlement program to provide health care benefits to persons 65 years of age or older, certain disabled beneficiaries, and most persons with end-stage renal disease. Once eligible, beneficiaries should not receive different benefits solely because their place of residence differs.

Since its inception, the program has grown considerably: The number of people with coverage increased from 19 million in 1967 to over 35 million. Currently, about 96 percent of those eligible for Medicare are enrolled. HCFA, within the Department of Health and Human Services, administers the Medicare program and establishes the regulations and policies under which the program operates.

The Medicare program consists of two distinct insurance programs. Part A (Hospital Insurance Benefits for the Aged and Disabled) covers services furnished by hospitals, home health agencies, hospices, and skilled nursing facilities. Part B (Supplementary Medical Insurance for the Aged and Disabled) covers a wide range of medical services and supplies--including physician services, outpatient hospital services, and home health services not covered under Part A, as well as diagnostic laboratory tests, x rays, and the purchase or rental of durable medical equipment.

In accordance with title XVIII of the Social Security Act, as amended, HCFA contracts with 34 private insurance carriers to process and issue benefit payments on claims submitted under Part B coverage. Carriers are required to process claims in a timely, efficient, effective, and accurate manner. During fiscal year 1993, carriers processed about 576 million Part B claims submitted by about 780,000 physicians and 136,000 suppliers.

The Social Security Act mandates that carriers pay only for services that are covered, and reject the claim if they determine that the services were not medically necessary. In fiscal year

1993, carriers denied 112 million Part B claims in whole or part (19 percent of all claims processed) for a total of $17 billion (which represented 18 percent of all billed charges, a figure unchanged from the previous year). The percentage distribution by reason of the dollar amount denied was as follows: duplicate claim (30 percent), service not covered (14 percent), claimant ineligible (8 percent), missing information (10 percent), rebundled (6 percent), filing limit exceeded (1 percent), Medicare secondary payer (6 percent), and other (16 percent). Services deemed not medically necessary constituted about 9 percent of the dollar amount denied by carriers.

With the exception of determination of medical necessity, the above reasons for denial are generally the result of routine administrative checks made during claims processing. Determining the medical necessity of a service, on the other hand, requires that carriers develop a medical policy that reflects local standards of medical practice and apply that policy in making determinations as to whether the billed service was performed in accordance with those standards. Carriers have been given broad latitude in this respect--that is, they have been given primary responsibility for defining the criteria that are used to assess the medical necessity of the services on a claim.

Concerning medical necessity, you asked us to assess whether there are differences among carriers with regard to the rates of claims denied for this reason, and to describe the characteristics of the types of claims denied. In response to your request, we analyzed data on claims processed by six carriers to ascertain rates of claims denied specifically for medical necessity. This testimony presents our results. Our analytical methodology is given in Appendix I. A forthcoming report will examine these issues as they relate to the question of claims appeals.

FINDINGS

Our study addressed the issue of consistency in denial rates for the 71 most utilized and costly services across the six carriers we examined. We have three findings to report.

First, we found sizable differences among the carriers with respect to denial rates for the services screened for medical necessity.[1] The denial rates for the top 71 services are

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[1]For the purpose of our analysis, we assumed that, if a carrier denied at least one service for reason of medical necessity, that carrier must have had a screen in place for that procedure code. It should be noted that, while a medical necessity denial constitutes evidence of the presence of a screen, the absence of denials for a particular procedure code, though strongly

presented in table 1, and show notable variability across carriers. For instance, the first line shows the denial rates for code 99213, billed for an office or outpatient visit (see Appendix II for a glossary of service codes), among the six carriers. For example, the Northern California carrier denied 0.4 services for every 1000 they allowed, while the Southern California carrier denied 3.7 services for every 1000 they allowed.

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suggestive, does not preclude the possibility that the carrier may have had a screen in place. However, given that the top 71 services generally have high utilization rates, such screens, if they existed, must have been fairly inefficient.

Table 1: Rates of Denial for Medical Necessity Per 1000 Services by Service Code and Carrier for 1992
(Top 71 Part B Service Codes, Ranked by Allowed Charges)

Code	N. CA	S. CA	NC	SC	IL	WI	*Sig.*
99213	0.4	3.7	0.3	0.0	3.7	9.7	*.01*
66984	0.2	10.8	5.5	0.0	1.1	0.0	*.01*
99232	0.9	13.7	0.4	1.7	11.9	17.1	*.01*
99214	0.2	4.4	0.3	0.3	3.8	8.2	*.01*
99231	0.3	12.4	0.3	2.2	13.4	21.5	*.01*
99212	0.6	7.9	0.5	0.0	5.5	18.4	*.01*
99233	0.8	22.9	0.3	2.1	9.1	20.4	*.01*
A0010	0.3	20.4	1.2	48.6	0.0	42.4	*.01*
93307	4.1	140.0	1.2	0.0	0.0	1.5	*.01*
88305	0.1	19.9	1.5	0.5	0.0	0.7	*.01*
99223	0.3	9.5	2.6	1.2	7.8	6.6	*.01*
99215	0.1	6.3	1.0	0.0	5.6	6.2	*.01*
99254	0.2	2.3	0.4	0.8	0.0	0.5	*.01*
66821	0.0	1.0	1.1	0.0	0.0	0.0	*N.S.*
A0220	0.4	10.8	0.0	47.2	0.0		*.01*
71020	0.4	12.4	0.9	0.2	103.2	0.9	*.01*
90844	0.2	9.9	1.0	0.0	0.0	0.7	*.01*
99222	0.6	11.3	1.5	3.1	9.8	2.5	*.01*
92014	0.1	2.8	1.0	0.0	2.5	83.5	*.01*
27447	0.0	2.9	0.0	0.0	0.0	0.0	*N.S.*
E1400	21.9	63.4	51.6	0.0	10.2	6.9	*.01*
99238	0.5	12.2	0.4	0.3	10.3	13.7	*.01*
93547	0.0	3.0	1.5	0.0	0.0	0.0	*N.S.*
80019	1.1	3.5	0.2	2.8	93.8	0.0	*.01*
99244	0.0	3.0	0.0	0.0	0.0	3.6	*.01*
A2000	77.1	72.2	173.9	116.5	142.8	18.3	*.01*
B4150		66.5		0.0	0.0		*.01*
77430	0.0	1.2	0.0	0.0	0.0	1.6	*N.S.*
B4035		66.8		0.0			*.01*
99255	0.4	2.6	0.0	0.0	0.0	0.0	*.01*
J9217	0.0	1.0	17.1	0.0	0.0	2.7	*.01*
90995	0.6	1.8	9.7	0.0	2.1	0.0	*.01*
93005	1.0	8.5	0.6	0.0	0.1	0.8	*.01*
92982	0.0	182.4	29.2	0.0	0.0	33.3	*.01*

Code	N. CA	S. CA	NC	SC	IL	WI	*Sig.*
99284	0.2	8.5	1.7	0.0	0.0	4.8	*.01*
99285	0.0	30.7	2.9	0.9	0.0	8.3	*.01*
45385	0.0	3.7	0.0	0.0	0.0	0.0	*N.S.*
92012	0.0	1.8	0.5	0.0	1.6	51.5	*.01*
45378	0.0	0.9	0.0	0.0	0.8	0.0	*N.S.*
99311	0.0	2.6	0.8	0.0	4.1	5.0	*.01*
71010	0.5	16.0	4.4	1.0	80.6	1.0	*.01*
00142	0.0	1.3	5.7	0.0	0.0	17.8	*.01*
E1401	22.4	35.5	17.7	0.0	19.6	14.0	*.01*
E1403	18.1	37.3	18.9	0.0	19.3	18.9	*.01*
33512	14.6	0.0	0.0	0.0	0.0	0.0	*N.S.*
99291	0.3	6.9	1.8	4.2	13.8	27.7	*.01*
Q0043	9.5	32.7	0.0	0.0	10.8	19.2	*.01*
93320	0.4	88.8	8.1	0.0	0.0	4.8	*.01*
99253	0.5	2.6	2.2	0.0	0.0	1.1	*.01*
52601	9.0	3.2	0.0	0.0	0.0	0.0	*N.S.*
99312	0.2	4.3	0.3	0.0	3.6	3.1	*.01*
99204	0.0	8.6	0.0	0.0	4.1	0.0	*.01*
93549	0.0	0.0	198.6	0.0	0.0	0.0	*.01*
99203	0.7	10.4	0.2	0.0	3.6	1.3	*.01*
43235	0.0	0.9	1.1	0.0	1.8	0.0	*N.S.*
43239	0.0	1.6	3.7	0.0	2.2	0.0	*N.S.*
A0020	6.2	74.3	1.4	18.4	0.1	49.5	*.01*
33513	3.9	0.0	0.0	0.0	0.0	0.0	*N.S.*
99283	0.1	12.5	1.0	0.8	0.0	14.7	*.01*
90843	0.2	14.7	1.6	0.0	0.0	1.0	*.01*
27130	0.0	4.7	0.0	0.0	0.0	0.0	*N.S.*
85025	0.9	5.2	0.2	0.0	0.0	0.3	*.01*
A0150	302.5	83.2	1.9	13.0			*.01*
84443	0.6	3.4	0.3	4.4	0.0	0.0	*.01*
93880	0.0	124.9	13.6	0.0	0.0	0.0	*.01*
36415	0.2	3.2	0.9	0.2	0.0	0.1	*.01*
99205	0.3	6.9	0.7	0.0	9.3	0.0	*.01*
00562	0.0	0.0	0.0	0.0	0.0	0.0	*N.S.*
76091	0.3	54.0	0.3	0.0	0.0	0.4	*.01*
83720	1.8	11.2	0.1	2.1	0.0	0.0	*.01*
99245	0.0	2.4	0.0	0.0	0.0	12.8	*.01*

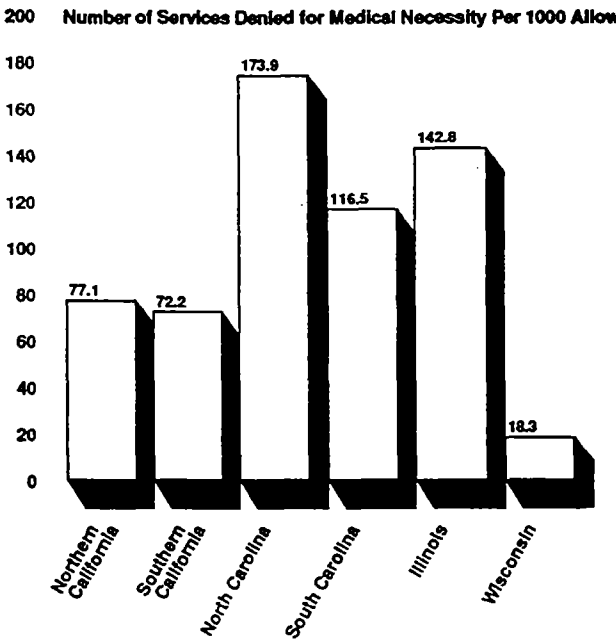
We found that for 58 of the 71 services shown in table 1, significant variations existed among carriers in the denial rates for medical necessity.

The following figures graphically illustrate this overall pattern by showing, across carriers, denial rates for three services: chiropractic (service code A2000); percutaneous transluminal coronary angioplasty, also known as PTCA (service code 92982); and critical care (service code 99291).

Looking at chiropractic services, we see that the rates of denial for medical necessity (per 1,000 services allowed) ranged from 18 to 174 among these six carriers. (See figure 1.) For PTCA, one carrier had a denial rate of 182, two had denial rates of about 30, while three carriers did not deny any services for medical necessity. (See figure 2.) Lastly, for critical care, while the overall range was smaller (0.3 to 27.7), there again was significant variation among carriers. (See figure 3.)

(Filename: C:OPCMEDFIG2)

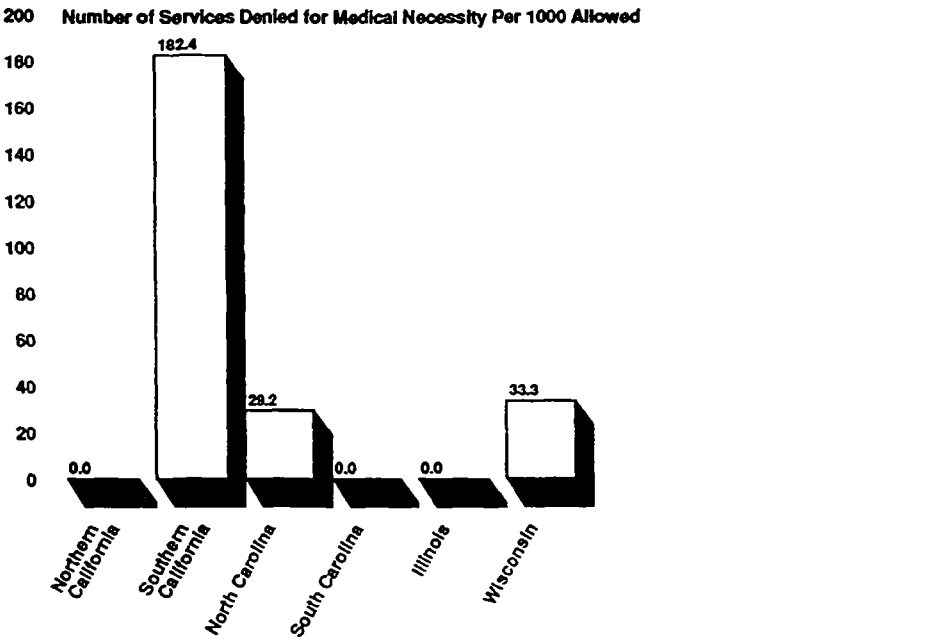
Figure 1: Variation in Denial Rates for Medical Necessity—Chiropractic Visits.



Note. Rates based on a 5 percent sample of 1992 Medicare Part B Claims.

(Filename: C:OPCMEDFIG3)

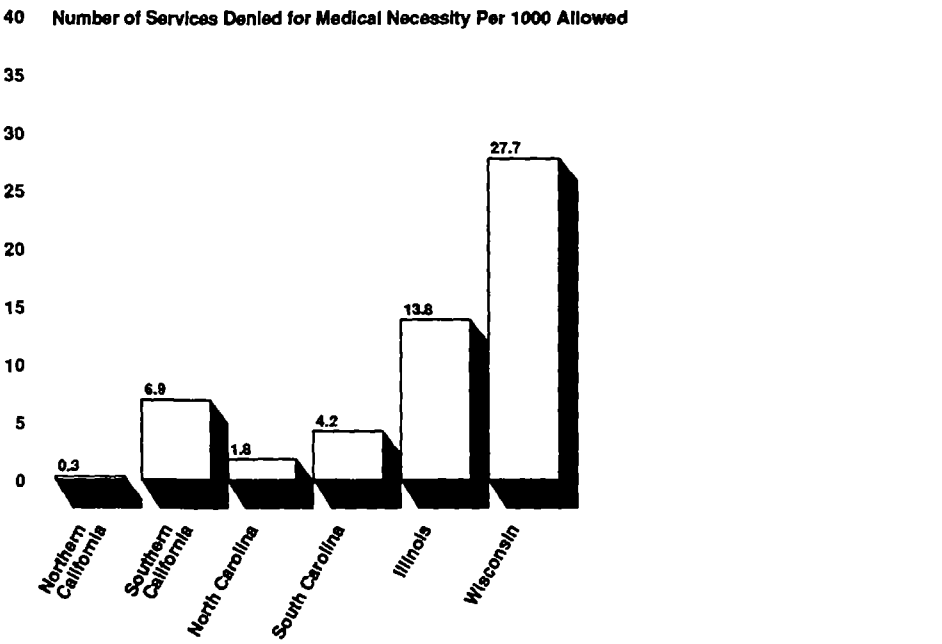
Figure 2: Variation in Denial Rates for Medical Necessity—Percutaneous Transluminal Coronary Angioplasty.



Note. Rates based on a 5 percent sample of 1992 Medicare Part B Claims.

(Filename: C:OPCMEDFIG4)

Figure 3: Variation in Denial Rates for Medical Necessity—Critical Care.



Note. Rates based on a 5 percent sample of 1992 Medicare Part B claims.

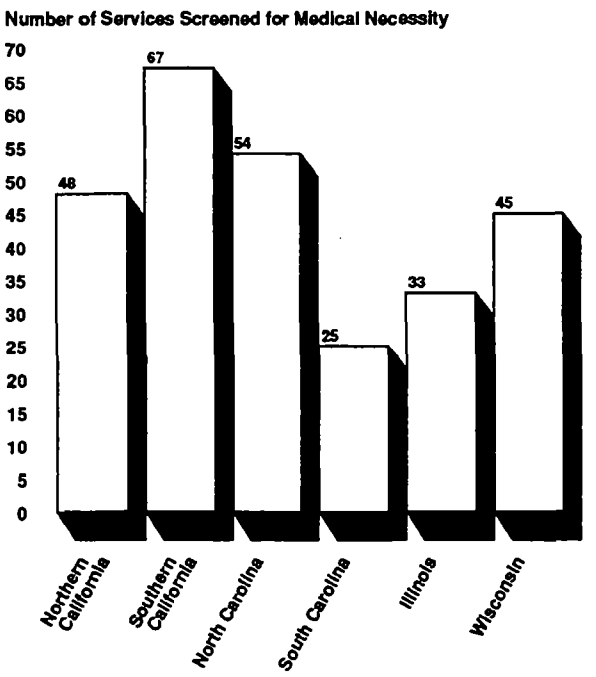
Second, we found that the number of services that carriers screened for medical necessity varied markedly. As shown in figure 4, some carriers had screens in place for almost all of the top 71 services, while others screened for little more than one third of these codes.[2]

Finally, our third finding is that the overall denial rate for medical necessity also differed among these six carriers. As shown in figure 5, at one extreme, one carrier denied as few as 1 service per 1,000 allowed, while at the other extreme, another carrier denied 23 services per 1,000 allowed.

[2]Service codes are also referred to as procedure codes.

(Filename: MEDFIG1)

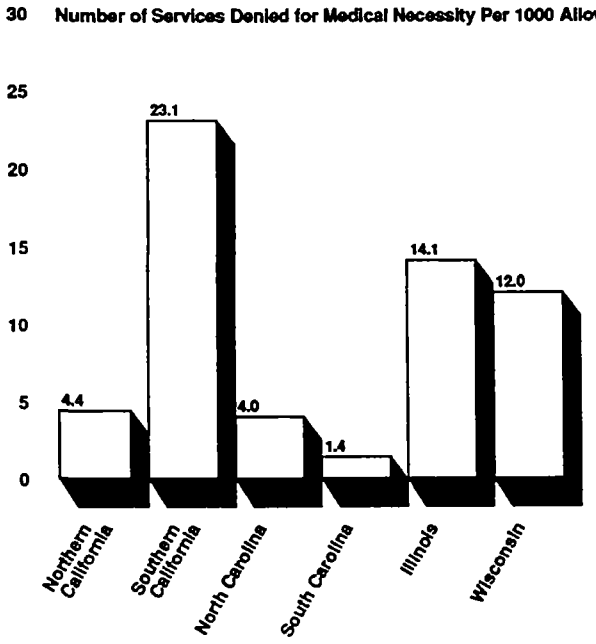
Figure 4: Number of Top 71 Services Screened for Medical Necessity by Carrier.



Note. Percentages based on a 5 percent sample of Medicare Part B claims processed in 1992. Top 71 services based on allowed charges.

(Filename: C:OPCMEDFIG5)

Figure 5: Variation in Denial Rates Among Carriers.



Note. Rates based on a 5 percent sample of 1992 Medicare Part B claims.

CONCLUSIONS

Significant variations exist among six Medicare Part B carriers in the ratio of medical necessity denials for 58 of the top 71 services. What do such differences in denial rates among carriers mean? The answer to this question depends on how these variations arise. Two plausible explanations have been advanced--with each having a different policy implication. One explanation focuses on differences in the medical policies used by carriers, while the other focuses on the billing practices of providers.

Variation Due to Differences in Medical Policy

The Social Security Act mandates that carriers pay only those Medicare Part B claims that are reasonable and medically necessary. Medicare law recognizes regional and local differences in medical practice and thus gives carriers broad latitude in defining the criteria for determining medical necessity. However, this latitude, in and of itself, produces some degree of variability in how similar claims are treated across carriers representing different geographic areas. That is, a policy cannot, at the same time, both allow for local variation in what is or is not viewed as medically necessary and also produce uniform results.

As our results show, carriers have in fact exercised this latitude. We found significant differences in both the number and types of services that are screened for medical necessity. Moreover, even when screening the same type of service, carriers used different working definitions of what is medically necessary.

For example, the first 12 visits to a chiropractor for spinal manipulation to correct a subluxation (code: A2000) must meet certain basic HCFA coverage criteria such as the following: An x ray must be available, if requested; signs and symptoms must be stated; and the precise level of subluxation must be reported. The carriers we spoke to had all incorporated these criteria into their medical policy for chiropractic spinal manipulation. HCFA requires that carriers assess the necessity of visits in excess of 12 per year, but carriers diverged in how they assessed such treatments. One carrier stated that, after 12 visits, additional documentation on medical necessity would be required. Another carrier set the number of additional visits allowed based on the injured area of the spine. When that number of additional visits was reached, this carrier required additional documentation from the provider. Still another carrier stated that, while they reviewed additional visits beyond the 12th, they usually did not require additional documentation until the 30th visit.

Given the broad variations found in denial rates across the

six carriers we examined, it would seem reasonable to conclude that some portion of that variance is due to differences in medical policies. Thus, one unintended consequence of setting medical policy locally is that, while it attempts to promote congruence between local medical policy and practice, viewed from a national perspective, it has also produced inconsistent treatment of Medicare providers and beneficiaries from one region to another, and one carrier to another.

Variations in Billing Practices

In our discussions with HCFA officials and representatives of the six carriers, it was asserted that difference in medical policy is but one possible explanation for variation in denial rates. Both the carriers and HCFA pointed to a second potential source for the observed variation in denial rates, one that focuses on differences in the billing practices of providers. Their explanation has several variants, which we summarize below:

- the various regions of the country have different levels of fraud and abuse, which in turn produce different denial rates;
- differences in denial rates could be due to aberrant billing practices by as few as two or three providers;
- in certain regions of the country, providers disregard the feedback they receive from denied claims--that is, they continue to bill for services they know are not medically necessary in the hope that some will be approved; and
- certain carriers do a better job of educating providers in how to submit Medicare claims correctly.

In sum, although at least two hypotheses can thus be advanced to explain the wide variation we found in the denial rates of our six carriers, it is important to note that (1) these findings are new: the size of this variation had not been previously examined by HCFA; and (2) HCFA is only now beginning to conduct evaluations to determine which, if either, of the above major explanations (that is, medical policy or billing practice) best accounts for the inconsistency we observed in denial rates. Given this lack of information, it has been difficult for HCFA to take a position on the question of whether a high or a low denial rate represents better public policy. HCFA officials told us that, although low denial rates are desirable from the standpoint that they imply less trouble for providers and beneficiaries, they are only desirable insofar as providers appropriately bill only for what is medically necessary. If providers are inappropriately billing Medicare, high denial rates are desirable.

The issue here, however, is not the size of denial rates, but rather their consistency. Medicare is not a local initiative. It is a national program under which beneficiaries should not receive different benefits solely because their place of residence differs. Yet we found that beneficiaries and providers have in fact been treated with considerable inconsistency by six carriers making individual determinations concerning what is and is not medically necessary. While it may be essential for Medicare to allow for local determination of medical policy, we found that this allowance, left to itself, leads to inconsistent treatment of beneficiaries and providers.

Carrier representatives told us they believe that inter-carrier variation would be reduced if HCFA established more national medical policies that define specific parameters for what is medically necessary. What is clear from our work to date, however, is that denial rates provide useful insight into how effectively Medicare contractors are managing program dollars and serving beneficiaries and providers. We believe that HCFA needs to play a greater role in using such data to oversee carriers' claims review activities to better assure that beneficiaries and providers are equitably treated.

Mr. Chairman, this concludes my remarks. I would be happy to answer any questions that you or members of the Committee may have.

METHODOLOGY

To develop the information in this testimony, we visited six carriers and analyzed claims processed by each of them. In selecting carriers, we considered two factors: geographic location and the number of claims processed.[3] Table I.1 lists the carriers we visited and the number of claims they processed in fiscal year 1992.

Table I.1: Selected Medicare Part B Carriers (Data for 1992)

Carrier	Geographic location	Number of claims processed (in millions)
California B/S	West	24
California-Occidental	West	25
Illinois B/S	Midwest	22
Wisconsin-Physician Srv.	Midwest	10
North Carolina-Conn. Gen.	Southeast	18
South Carolina B/S	Southeast	8

Taken together, these six carriers processed about 19 percent of all Part B claims in fiscal year 1992; however, because of our judgmental selection process, we cannot generalize our findings to the universe of carriers.

[3]Our sample included two carriers from each of the following three regions: the Southeast, the Midwest, and the West. In making this selection, we sought to maximize the geographic distance between regions, while at the same time retaining the potential for examining intraregional variation in medical policies. In terms of the number of claims processed, the frequency distribution of carriers is essentially bimodal--that is, there are two large clusters of carriers, those that annually process between 2 and 13 million claims and those that process between 18 and 29 million claims (2 carriers processed over 46 million claims each). Our sample included two carriers from the former cluster and four from the latter.

Source of Data

To compare medical necessity denial rates among carriers, we obtained from HCFA a 5 percent sample of 1992 Medicare Part B claims for the above six carriers. This information was abstracted from the physician/supplier portion of the Common Working File, which serves as a repository for all Medicare claims.

The Common Working File contains information on many claims-related variables, including the type of billed service and the action that was taken as a result of the claim review process. Medicare claims can contain submitted charges for more than one service; a claim for a simple medical checkup, for example, may include both the doctor's fee as well as the charge for lab tests performed during the visit. On the Medicare claim form, each billed service, or line item, appears as a separate charge with a corresponding five-digit service code that describes the type of service provided (for example, office visit, chiropractic treatment, and so on). Each of these services listed as a separate line item is subject to approval or denial by the carrier. During claims processing, carriers assign an action code to each line item that indicates that it was paid or, if denied, the reason for denial.[4]

In our analysis, we focused on two line item variables--the service and the action code. In calculating denial rates presented in our statement, we contrasted the number of services denied for lack of medical necessity with the total number of services allowed for a given service. Services denied for other reasons were excluded from the analysis.

Because there are more than 10,000 different service codes, we ranked service codes in terms of the total of allowed charges (in 1992), and then restricted our analysis to the top 71 codes.[5] Services that rank high in allowed charges are those that have high utilization rates and/or high cost per service. The top 71 service codes constitute approximately 50 percent of all Medicare Part B allowed charges.

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[4]Reasons for line item denial included in the Common Working File are: benefits exhausted, non-covered care, invalid care, duplicate line item, medically unnecessary, reprocessed adjustment, secondary payer, and other.

[5]The "allowed charge" is set by HCFA. The amount actually paid by HCFA is 80 percent of the allowed charge less deductible and/or co-payment.

Sampling Considerations

The 5-percent sample used in our analysis was extracted from the Common Working File by keying on the last two digits of the beneficiary identification number. This method is commonly used by HCFA, and while we have no reason to believe that it is biased, it is not, strictly speaking, a random sample, but rather an approximation of a random sample. Consequently, the tests of statistical significance presented in this testimony are included mainly for heuristic purposes: that is, to identify those codes where carriers had especially large differences in denial rates.

To avoid unstable estimates of denial activity for certain service codes with low frequencies, we focused on the top 71 services (based on allowed charges). This group of services generally has high utilization rates and thus sufficiently large frequencies for making inter-carrier comparisons of denial rates.

LIST OF TOP 71 PROCEDURE CODES RANKED BY ALLOWED CHARGES FOR 1992

Procedure Code/ Narrative Description
99213 Office or other outpatient visit
66984 Extracapsular cataract removal
99232 Subsequent hospital care, per day
99214 Office or other outpatient visit
99231 Subsequent hospital care, per day
99212 Office or other outpatient visit
99233 Subsequent hospital care, per day,
A0010 Ambulance service, basic life support
93307 Echocardiography, real-time with image documentation (2D)
88305 Level IV - surgical pathology, gross and microscopic examination
99223 Initial hospital care, per day
99215 Office or other outpatient visit
99254 Initial inpatient consultation for a new or established patient
66821 Discussion of secondary membranous cataract
A0220 Ambulance service, advanced life support
71020 Radiologic examination, chest, two views, frontal and lateral
90844 Individual medical psychotherapy by a physician
99222 Initial hospital care, per day
92014 Ophthalmological services: medical examination and evaluation
27447 Arthroplasty, knee, condyle and plateau
E1400 Oxygen concentrator
99238 Hospital discharge day management
93547 Combined left heart catheterization, selective coronary angiography
80019 Automated multichannel test
99244 Office consultation for a new or established patient
A2000 Manipulation of spine by chiropractor
B4150 Enteral formulae; category I
77430 Weekly radiation therapy management
B4035 Enteral feeding supply kit; pump fed, per day
99255 Initial inpatient consultation for a new or established patient,
J9217 Leuprolide acetate, for depot suspension, 7.5MG
90995 End stage renal disease (ESRD) related services, per full month
93005 Electrocardiogram, routine ECG with a least 12 leads
92982 Percutaneous transluminal coronary angioplasty
99284 Emergency department visit
99285 Emergency department visit
45385 Colonoscopy, fiberoptic, beyond splenic flexure
92012 Ophthalmological services: medical examination and evaluation
45378 Colonoscopy, fiberoptic, beyond splenic flexure
99311 Subsequent nursing facility care, per day
71010 Radiologic examination, chest
00142 Anesthesia for procedures on eye

E1401 Oxygen concentrator, manufacturer specified maximum rate greater than 2
E1403 Oxygen concentrator, manufacturer specified maximum rate greater than 4
33512 Coronary artery bypass, autogenous graft
99291 Critical care, including the diagnostic and therapeutic services
Q0043 Stationary liquid oxygen system rental, includes contents (per unit)
93320 Doppler echocardiography, pulsed wave and/or continuous wave
99253 Initial inpatient consultation for a new or established patient,
52601 Transurethral resection of prostate
99312 Subsequent nursing facility care, per day
99204 Office or other outpatient visit
93549 Combined right and left heart catheterization
99203 Office or other outpatient visit
43235 Upper gastrointestinal endoscopy including esophagus
43239 Upper gastrointestinal endoscopy including esophagus
A0020 Ambulance service, (BLS) per mile, transport, one way
33513 Coronary artery bypass, autogenous graft
99283 Emergency department visit
90843 Individual medical psychotherapy by a physician
27130 Arthroplasty, acetabular and proximal femoral
85025 Blood count
A0150 Non-emergency transportation, ambulance, base rate one way
84443 Thyroid stimulating hormone (TSH), RIA or EIA
93880 Duplex scan of extracranial arteries
36415 Routine venipuncture for collection of specimen(s)
99205 Office or other outpatient visit
00562 Anesthesia for procedures on heart, pericardium
76091 Mammography;
83720 Lipoprotein cholesterol fractionation calculation by formula
99245 Office consultation for a new or established patient

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