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Sarah —
If you're going to do this, you better talk w/ OIRA & others very soon. What you think? Please advise.

TELECOPIER COVER SHEET

Date: 7/15/99 **Time:** 12:12 PM

Fax No.: 202-456-5557 **Client No.:** 0012

To: Chris Jennings, Congressional Liaison for Health Policy

From: Steve Jenning

Number of Pages (excluding cover sheet) 8

Person Sending: Steve Jenning

Chris: Per our prior communications on restraint regulations, here is a legal opinion indicating severe problems with the agency rulemaking.

for your 2:30 mtg

IF YOU HAVE ANY PROBLEMS RECEIVING, PLEASE CALL PERSON SENDING IMMEDIATELY

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July 15, 1999

Via Hand

Mark Covall
Executive Director
National Association of Psychiatric Health Systems
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Washington, D.C. 20004-1105

Re: Conditions of Participation—Restraint Rules

Dear Mark:

You asked us to review whether the interim final rule on Conditions of Participation ("CoP"), issued by the Health Care Financing Administration ("HCFA") on July 2, 1999, comports with the provisions of the Regulatory Flexibility Act ("RFA"), 5 U.S.C. §§ 601 *et seq*. As you know, the RFA was amended by the Small Business Regulatory Enforcement Fairness Act of 1996, title II, Pub. L. 104-121, to provide for judicial review. *See* 5 U.S.C. § 611(a)(1).

The interim final rule, as discussed below, raises significant issues under the RFA.[1] In our view, the purported regulatory analysis published in the preamble fails to comply with the requirements of the RFA. In particular, the provision of the CoP that would likely have the greatest financial impact on both free-standing psychiatric hospitals and general acute care hospitals, namely the requirement that a physician (or other licensed independent practitioner) examine a patient within

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1 The interim final rule also raises significant issues under section 1102 of the Social Security Act, which requires HCFA to determine the cost of the rule on rural hospitals. HCFA claimed that the rule would have no effect on rural hospitals; this is clearly incorrect given the need to hire additional physicians to implement the one-hour rule. We also believe that the rule raises significant issues under the Unfunded Mandates Reform Act of 1995 and the congressional review provisions of the Contract with America Advancement Act of 1996, Pub. L. 104-121, codified at 5 U.S.C. §§ 801 *et seq*.

one hour of being placed under a restraint or in seclusion, was never factored into the regulatory analysis performed by HCFA. This is particularly troublesome since the notice of proposed rulemaking did not contain a "one-hour" rule and, therefore, the economic impact of it on small health care providers was never analyzed. As discussed below, we estimate that the one-hour requirement will cost hospitals in excess of $50 million annually to implement and the corresponding benefits will be, as the Secretary candidly noted, immeasurable. In addition, certain facts relied upon by HCFA in performing its regulatory analysis are simply wrong. The correct information could have been easily obtained by HCFA, and if it had been used, it too would have affected HCFA's analysis.

The interim final CoP rule requires hospitals to implement a series of procedures and polices designed to safeguard patients who are restrained for medical or behavioral reasons. Among the many prophylactic requirements is one that in cases where seclusion or a restraint is used for behavior management, a "physician or other licensed independent practitioner must see and evaluate the need for restraint or seclusion within 1 hour after the initiation of this intervention." 64 Fed. Reg. 36069, 36089 (July 2, 1999), to be codified at 42 CFR § 482.12(f)(3)(ii)(C). In the preamble to the rule, the Secretary has not certified that the rule would not have a significant effect on small businesses. Thus, the Secretary was required to undertake a flexibility analysis. Instead, the Secretary and HCFA noted that "we have no factual reports, studies, or data to aid in the development of cost or savings estimates." 64 Fed. Reg. at 36086. The Secretary goes on, however, to claim that since "most hospitals are already fulfilling many of the requirements of this regulation . . . there may be no significant increase in the burden to most hospitals." *Id.* Correspondingly, the Secretary asserts that with respect to the "restraint and seclusion standards, . . . there should be no significant additional burden for, at least, the 80 percent of the Medicare participating hospitals accredited by JCAHO since the requirements are modeled on JCAHO's standards . . . ." *Id.* These claims are simply wrong and underscore the fact that, putting aside the preamble's hortatory language, the Secretary failed to even attempt the type of regulatory analysis required by the RFA. In particular, the one-hour requirement is a major change in practice and is not a current JCAHO standard. In fact, JCAHO requires a physician or licensed independent practitioner to order restraint or seclusion, but the physician does not have to conduct a face-to-face evaluation for 24 hours. *See* JCAHO STANDARDS TX.7.1.3.1.7 and TX.7.1.3.1.8 (Nov. 1998).

The Regulatory Flexibility Act requires administrative agencies, such as HCFA, to consider the effect of their actions on small entities, small non-profit enterprises, and small local governments. A small entity is either a nonprofit organization or a small business under 15 U.S.C. § 632. *See* 5 U.S.C. § 601. As the

Secretary acknowledged in the preamble, "we treat most hospitals . . . as small entities, either by virtue of their nonprofit status or by having revenues of $5 million or less annually." 64 Fed. Reg. at 36085. Under the RFA, an agency that publishes a notice of proposed rulemaking must prepare an initial regulatory flexibility analysis describing the effect of the proposal on small businesses and discussing alternatives that might minimize the adverse economic consequences. *See* 5 U.S.C. § 603. When an agency issues its final rule, it must undertake and publish a final regulatory analysis, which provides the following[2]:

(1) a succinct statement of the need for, and objectives of, the rule;

(2) a summary of the significant issues raised by the public comments in response to the initial regulatory flexibility analysis, a summary of the assessment of the agency of such issues, and a statement of any changes made in the proposed rule as a result of such comments;

(3) a description of and an estimate of the number of small entities to which the rule will apply or an explanation of why no such estimate is available;

(4) a description of the projected reporting, recordkeeping and other compliance requirements of the rule, including an estimate of the classes of small entities which will be subject to the requirement and the type of professional skills necessary for preparation of the report or record; and

(5) a description of the steps the agency has taken to minimize the significant economic impact on small entities consistent with the stated objectives of applicable statutes, including a statement of the factual, policy, and legal reasons for selecting the alternative adopted in the final rule and why each of the other significant alternatives to

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[2] An agency may avoid conducting a regulatory analysis if the head of the agency certifies that the rule "will not . . . have a significant economic impact on a substantial number of small entities." 5 U.S.C. § 605. A certification under section 605 must itself be based on data and cannot be used as a ruse to avoid an analysis. *See Northwest Mining Association v. Babbitt*, 5 F. Supp. 2d 9, 15 (D.D.C. 1998) (setting aside a certification because it "was without observance of procedure required by law"). Here, the Secretary filed no certification, and therefore, a full impact analysis was required.

> the rule considered by the agency which affect the impact on small entities was rejected.

5 U.S.C. § 604(a) (Supp. 1997).

We believe that HCFA failed to comply with the RFA requirements concerning an estimate of the number of small entities affected (requirement 3), and a description of the steps taken to minimize the rule's impact on small businesses, including a list of the less costly alternatives considered and the reasons why they were rejected (requirement 5).

As noted above, HCFA stated that it lacked the necessary information to conduct a real cost benefit analysis. Accordingly, it relied on newspaper articles and other questionable sources for its qualitative assessment. Indeed, it made no effort to quantify the number of small entities that would be affected by the rule, especially its one-hour provision. That information, however, was readily available to HCFA in its own Part A database and certainly could have been obtained from industry sources. Specifically, there are, at minimum, 200 freestanding psychiatric hospitals that do not employ physicians 24 hours per day. Thus, to ensure compliance with the one-hour requirement, each of these psychiatric hospitals would need to employ or contract with at least two full-time equivalent physicians to provide appropriate coverage at an estimated annual cost to each hospital of $250,000. This is so, because most freestanding psychiatric hospitals have physicians on-call around the clock and have immediate access to nearby acute care hospitals in the event of a medical emergency, but few, if any, are staffed by physicians 24 hours per day. A similar situation would exist in many general acute care hospitals—especially those in rural communities—thereby further increasing the economic impact of the rule. In short, the one-hour requirement would increase costs by at least $50,000,000 to just these 200 psychiatric hospitals; we view that as a significant adverse affect on these small institutions. Moreover, given that the rule goes into effect 30 days after publication, the cost of retaining qualified physicians in such a short time may be higher than it ordinarily would have been.

An agency is not free to ignore existing data by claiming it is not readily available. Thus, in *North Carolina Fisheries Association, Inc. v. Daley*, 27 F.Supp.2d 650 , 659-60 (E.D.Va. 1998), the court chastised the Commerce Department for ignoring existing data and relying on internally generated data that the Department knew were inaccurate. Here, as in *Daley*, the government is attempting to "soft-pedal[ ] around the documented results." *Id.*

Given the significant economic impact of the one-hour requirement, the agency should have considered less costly alternatives. It did not, and therefore

clearly failed to fulfill its obligation under the RFA "to consider less severe alternatives." *Id.* In particular, HCFA totally failed to even mention, let alone consider, the current and accepted practice under which nurses with demonstrated competence provide the physician with the short-term clinical information necessary for the physician to make an informed decision, albeit not face-to-face.

Instead, the agency implied that the costs would be minimal because JCAHO-accredited hospitals already comply, as a condition of accreditation, with the one-hour requirement. Such is not the case. As noted above, JCAHO standards do not require a physician to be present on premises around the clock, nor do state laws impose similar restrictions. JCAHO requires that a physician or licensed independent practitioner examine a patient within 24 hours after that patient has been placed in restraints or seclusion. The one-hour requirement, far from being in harmony with existing accreditation standards, will dramatically change current standards and practices. In short, the interim final rule would impose a new, costly requirement. That requirement, however, was never subjected to the type of scrutiny required by the RFA. Quite to the contrary, the agency abdicated its statutory responsibilities under the RFA when it stated that "we have no factual reports, studies, or data to aid in the development of cost or savings estimates." 64 Fed. Reg. at 36086. This is insufficient.

Accordingly, we recommend that you request that the Secretary and HCFA delay the effective date of the interim final rule until such time as HCFA has had the opportunity to conduct the type of flexibility analysis required by Federal law.

Sincerely yours,

Robert P. Charrow

The National Association of Psychiatric Health Systems

Issue Brief

HCFA CONDITIONS OF PARTICIPATION: PHYSICIAN* MONITORING OF SECLUSION AND RESTRAINT (Proposed Modification)

July 14, 1999

SUMMARY OF ISSUE

The Health Care Financing Administration (HCFA) has issued standards on the use of restraint and seclusion for behavioral health management. The standards will take effect as "Conditions of Participation" 30 days following the July 2, 1999 *Federal Register* notice of the Interim Final Rule and will apply to hospitals participating in the Medicare and Medicaid programs.

In releasing these (and other patient protection standards), HCFA noted its intent to ensure patients "freedom from the inappropriate use of restraints and seclusion" and to make its standards consistent with those of the Joint Commission on Accreditation of Healthcare Organizations (JCAHO).

The American Hospital Association (AHA) and the National Association of Psychiatric Health Systems (NAPHS) believe that a new requirement on physician* monitoring of seclusion and restraint – which was not part of the original proposed rule – and the 30-day effective date for implementing such a substantial change in current practice would create unintended, costly and serious patient care problems. We believe the standards need to assure physician accountability while providing flexibility for clinical judgment and practice.

OUR VIEW

AHA and NAPHS support HCFA's leadership in issuing standards on restraint and seclusion. We believe that the regulatory process is the appropriate way to address any concerns about restraint and seclusion, and we recently wrote to HCFA encouraging them to issue final Medicare and Medicaid hospital Conditions of Participation relating to the use of restraint and seclusion for behavioral health management. (These provisions were part of a larger set of possible revisions to Conditions of Participation pending since December 19, 1997.) We believe that HCFA's issuance of regulations is the most effective way to provide accountability without hindering patient safety or confidentiality.

* or licensed independent practitioner (LIP)

AHA's and NAPHS's most serious concern is about one specific standard in the July 2, 1999 interim final regulation that refers to physician monitoring of restraint and seclusion. This language was ***not*** in the original December 19, 1997 proposed rule on which comments were solicited and appeared for the first time in the July 2, 1999 Interim Final Rule, which becomes effective in 30 days. Currently, this new provision on physician monitoring of restraint and seclusion says:

> (f) Standard: Seclusion and restraint for behavior management
> (3) (ii) C A physician or other licensed independent practitioner must see and evaluate the need for restraint or seclusion within 1 hour after the initiation of this intervention.

We fully support the concept of physician accountability and involvement in a timely manner whenever a patient's condition requires the use of restraint or seclusion. However, as written, we believe this provision would create unintended, costly consequences without evidence that it will improve patient care. This provision presents several problems.

- **This regulation inappropriately dictates medical practice.** It is not feasible, clinically necessary or economically viable to require a face-to-face physician evaluation in every case. It *is* appropriate to require a timely and clinically appropriate evaluation. We support the physician's role and responsibility in the overall evaluation and assessment of the patient. A physician assessment should always be done, but the physician should be the one to determine whether a face-to-face evaluation is necessary within one hour.

- This regulation **would increase costs** dramatically. HCFA's impact analysis contends that 80% of hospitals would not be affected by this provision because they are JCAHO accredited. In fact, **no valid cost impact analysis of this provision was conducted.** Many hospitals would be adversely affected because this is *not* the current JCAHO standard. This would result in major increases in cost at a time when resources available for the delivery of psychiatric services are as low as they have ever been. For example, a February 1998 Health Economics Research study on the impact of the "Balanced Budget Act of 1997" payment reductions to psychiatric facilities found that the mean Medicare revenue margin would be -8.7%.

- There is **no empirical evidence** to base the assumption that a face-to-face evaluation by a physician or licensed independent practitioner within 1 hour will improve the outcome of care for patients who are restrained or secluded.

- This regulation **is not consistent with HCFA's stated intent "to revise all of the hospital Conditions of Participation" in concert with Vice President Gore's Reinventing Government (REGO) initiative"** (page 86 in 7/2/99 Interim Final Rule). The REGO initiative emphasized decreasing federal regulation to eliminate unnecessary structural and process requirements, focus on outcomes of care, allow greater flexibility to hospitals and practitioners to meet quality standards, and to place a stronger emphasis on quality assessment and performance improvement.

- This regulation **is not consistent with JCAHO standards** – which was HCFA's stated intent for the new Conditions of Participation. It would require implementation almost overnight of a **substantial change in current practice** by allowing *only* a face-to-face evaluation of a patient. It is important that physicians be able to use clinical judgment in

how evaluations are best accomplished based on the needs of the patient. Evaluations can be done in ways other than face-to-face as long as there are nurses with demonstrated competence on site to provide clinical input to inform the physician's decision.

- The specific language in this provision was *not* included in the proposed rules upon which comments were solicited from the field. This provides **inadequate time for comment** on a new provision with dramatic impact on the field.

RECOMMENDATIONS

1. Much of this new provision was never included in the original draft of the Conditions of Participation and will be virtually impossible to implement within the short 30-day timeframe that the regulation becomes effective. **We urge delay of its implementation** until there has been full analysis of the provision's real impact and the impact of the alternate proposal detailed below.

2. To ensure that this standard is consistent with JCAHO requirements and works to ensure the best interests of patients, **AHA and NAPHS recommend the following revision**.

> "A physician, or other licensed independent practitioner, must ~~see and~~ evaluate the need for restraint or seclusion within 1 hour after the initiation of this intervention." This evaluation may be done by the physician or licensed independent practitioner in consultation with a registered nurse who has demonstrated competency in the evaluation of a patient in restraint or seclusion and who is in face-to-face contact with the patient.

This language would allow for the following:

- The qualified registered nurse would, in many cases, be more readily accessible in the emergency situation that precipitated the restraint episode. Because of his/her involvement from the earliest stages of the event, the registered nurse would be able to provide added understanding of the situation. He/she would also be in a position to rapidly provide appropriate consultation so that the physician can make an informed evaluation. He/she could carry out the physician's orders and direct staff in the use of least restrictive methods and in the discontinuation of restraint or seclusion at the earliest possible time, as specified in the proposed regulations.

For more information, contact:

American Hospital Association: Karen Milgate, 202-626-4628 or Curtis Rooney, 202-626-2678
National Association of Psychiatric Health Systems: Cidette Perrin, 202-393-6700, Ext. 17

THE FREEDOM FROM RESTRAINT ACT OF 1999

SUMMARY OF THE NEW LEGISLATION

This legislation would essentially expand the requirements governing the use of restraints and seclusion in nursing homes to include hospitals participating in the Medicare and Medicaid program and intermediate care facilities for the mentally retarded, hospices, residential treatment centers for children and institutions of mental disease participating in the Medicaid program. This new legislation would allow these facilities to impose physical restraints only upon the written order of a physician and only when necessary to ensure the physical safety of the patient or of other patients. Providers would be required to report all instances of serious patient injury or death related to the use of restraints to a central database to be established by the Secretary. HHS would be required to ensure that the provider investigated the cause of the patient injury and death and established a strategy to prevent similar injuries.

SUMMARY OF THE HARTFORD CASES

The Freedom From Restraint Act of 1999 was inspired by a series of cases in Connecticut during October of 1998 in which several mentally ill children residing in psychiatric institutions died after being restrained by facility staff. The Harvard Center for Risk Analysis estimates that between 50 and 150 such deaths occur annually across the country. Reports indicated that many of the restraints being used routinely in the Connecticut facilities are not supposed to be used as part of patient care. A number of the patients died in the same type of a restraint hold, in which a patient is restrained face down on the floor, with their arms crossed beneath them and a staff member exerting pressure on their backs. In addition, there were indications that the restraining holds were not used as a last resort, but rather as a routine method of discipline. For instance, one of the children who died was restrained because he became upset after he was unable to find his favorite teddy bear.

HCFA PROPOSAL

HCFA has been aware of patient advocate concerns about the inappropriate use of restraints for over a year. In response, HHS published an NPRM in December of 1997 that proposed to modify the Medicare Conditions of Participation for hospitals to prohibit the use of seclusion or restraints except when in accordance with a patient's plan of care and should be used only as a last resort. Providers would be required to use restraints in the least restrictive manner possible and must be removed at the earliest possible time.

At this point, despite the fact that comments were submitted to the agency in April of 1998, HCFA has not taken steps to codify these conditions of participation into a final rule. However, because of the importance of this issue to the health and safety of patients, HCFA will carve out the Patients Rights section of the new Conditions of Participation. This section, which addresses the use of restraints, will be published in final form by late summer.

On a staff level, HCFA has objected to Senator Lieberman's proposal to create a centralized database to track patient deaths and injuries caused by the inappropriate use of restraints because of privacy concerns.

THE NEW LEGISLATION BUILDS ON HCFA'S CURRENT AUTHORITY

Currently, HCFA only has authority to require Medicare and Medicaid hospitals to comply with the standards for the use of restraints proposed in the NPRM. Senator Lieberman's proposed legislation would provide HCFA with the authority to require intermediate care facilities for the mentally retarded, hospices, residential treatment centers for children, and institutions of mental disease that are participating in the Medicaid program to comply with stricter standards around the use of patient restraints.