6

JUL 14 2006

Washington County Ambulance, Inc.

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7/10/2006

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1317-P
PO Box 8017
Baltimore, Maryland 21244-8017

To Whom It May Concern:

I am writing you en-regard to CMS Proposed Rule entitled "Medicare Program; Revisions to the Payment Policies of Ambulance services under the Fee Schedule for Ambulance Services." First of all I am confused on how Washington County is no longer considered a rural county by your new proposed rule. Washington County has 556.75 square miles and a population of 19612 from the last census. We are a farming community; Washington County has lost two of its biggest employers in the last few years from factory shut downs and moving jobs over sees and out of state.

Why are we being put into a metropolitan community is it just because we border a metropolitan county? Yes there are people that commute to the larger county because they have to work and provide an income for their families. I know of several counties in Iowa that are larger than Washington County that are still considered rural. I think your system is wrong and I would invite you to come to Iowa or any other county you are changing from rural to metropolitan before you make your final decision to see how rural some of these counties are.

Because all you are doing is shifting the cost of ambulance service to people who have insurance and to the tax payers of our county. With these cuts in mileage and the on going increase of operating an ambulance due to increasing fuel prices we will have no choice but to increase our fees.

I understand you are trying to keep cost down on your Medicare budget. But I hope you take a long hard look into this before you make a decision that could put several communities in jeopardy of losing there ambulance services from these cuts. Our call volumes are not going up because we are not a growing community and we all know that ambulance services operate on how many calls we do and transport people to the hospital that need to be transported.

I would be glad to talk with any of your staff about this matter at any time. Thanks for time into reading my comments.

Sincerely,

Richard L Young, Director
Washington County Ambulance.

INTERNATIONAL ASSOCIATION OF FIRE CHIEFS

Providing leadership for the fire and emergency services since 1873

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July 13, 2006

JUL 14 2006

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1317-P
Mail Stop C4-26-05
7500 Security Blvd,
Baltimore, MD 21244-1850

Re: CMS-1317-P; Medicare Program; "Revisions to the Payment Policies of Ambulance Services under the Fee Schedule for Ambulance Services"

The International Association of Fire Chiefs (IAFC) is pleased to provide comments on the Centers for Medicare and Medicaid Services (CMS) Proposed Rule entitled "*Medicare Program; Revisions to the Payment Policies of Ambulance Services under the Fee Schedule for Ambulance Services*" (71 Fed. Reg. 30358) published in the Federal Register on May 26, 2006. The IAFC represents fire service based entities that provide a full range of Emergency Medical Services (EMS) throughout the United States. The comments submitted herein by the IAFC are submitted on behalf of our 12,500 individual member agencies.

The IAFC was a representative to, and actively participated in, the Negotiated Rulemaking Committee (NRC) process that created the framework for the Ambulance Fee Schedule in 2002. As such, many of our comments refer to the Consensus Committee Statement signed by the members of the Negotiated Rulemaking Committee on February 14, 2000. It is our opinion that many of the changes outlined in the latest Proposed Rule are in conflict with the consensus material agreed to by the NRC members. Additionally, it is the opinion of the IAFC that many of the proposed changes will have a profound impact on many of our constituents in their delivery of pre-hospital emergency health care.

1. Background

The Balanced Budget Act of 1997 (BBA) mandated the development of a fee schedule for the reimbursement of ambulance services. This national fee schedule was designed to replace the existing system of reimbursing ambulance services based on the reasonable costs of a provider or the reasonable charges of a supplier. In order to create the national fee schedule, the BBA mandated that certain aspects of this ambulance fee schedule be developed through a Negotiated Rulemaking process involving various national organizations representing entities which furnish and regulate Emergency Medical Services

(EMS). As identified above, the IAFC was one of the organizations chosen to participate in the development of the fee schedule. The predecessor to CMS, the Health Care Financing Administration (HCFA), was also a member of the NRC and agreed to all of the items contained in the Consensus Committee Statement signed in February 2000. In April 2002, the new Ambulance Fee Schedule (AFS), as the final product became known, was implemented by Medicare. Not only did the new AFS create a more uniform payment system under Medicare for ambulance services, this was also the first major attempt by the Federal Government to work with the constituent groups on modifying the original ambulance regulations adopted with the advent of Medicare. Since then, HCFA and now CMS have both published clarifications to the AFS. However, until this latest Proposed Rule, there has never been an attempt by HCFA or CMS to unilaterally change the material agreed to by all of the constituent groups involved in the BBA mandated NRC process. Our organization is concerned with this development and has the following specific comments to offer:

2. **Comments on Adoption of New Geographic Standards**
   "CBSAs-REVISED OMB METROPOLITAN AREA DEFINITIONS"
   "RUCAs-RURAL URBAN COMMUTING AREAS"

The IAFC agrees with the CMS proposal to change the methodology used to identify areas that are considered "rural" or "urban." This includes the use of the Core Based Statistical Areas (CBSA) and Rural Urban Commuting Areas (RUCA). However, the IAFC would like to see a phased in approach to dealing with suppliers currently operating in areas identified as "rural" who will see a decrease in their payments once their responses are categorized by the new statistical tools as being in an "urban" area. This phased in approach has been used by CMS when implementing several other programmatic changes that resulted in reduced payments to hospitals, providers or suppliers. It is our opinion that the utilization of a phased in approach will allow those member agencies impacted by the proposed changes to adequately plan for the reduction in reimbursement resulting from a change in pick-up point designation from "rural" to "urban."

3. **Comments on Specialty Care Transport**
   "SPECIALTY CARE TRANSPORT"

The IAFC is concerned with the unilateral change being made by CMS to the definition of what constitutes a Specialty Care Transport (SCT). The definition of a SCT was determined by a consensus of all of the parties involved in the NRC. This consensus was reflected in the Consensus Committee Statement signed in February 2000, of which HCFA (now CMS) was signatory. It is the opinion of the IAFC that the previously agreed upon definition of SCT needs to be maintained until the same parties involved in the original NRC process can be brought back together as a group to once again come to consensus on the proposed changes.

Additionally, while CMS has identified that it considers the transfer of a patient between ground and air ambulances as an eligible SCT transport, the IAFC is concerned that once the hospital-to-hospital language is adopted, the carriers will no longer allow ground based suppliers to bill for SCT where the origin or destination uses the "I" modifier. The "I" modifier is used by suppliers to identify an intermediate stop enroute to the final

destination, and is used primarily by our members to show a pick-up or drop off at an aeromedical landing zone. Once CMS publishes the hospital-to-hospital only requirement, it is the fear of the IAFC that any transport using the "I" modifier will be disallowed by the Carriers as a non-covered service. While CMS might be of the opinion that these transports will ultimately be reimbursed following the completion of the appeal process, it is the opinion of the IAFC that CMS needs to take measures beforehand to ensure that these types of claims are not denied in the first place. With ambulance reimbursement rates down dramatically for many of our members, the added cost of undergoing the appeal process is onerous and cost prohibitive.

4. **Comments on Recalibration of the Ambulance Fee Schedule Conversion Factor "RECALIBRATION OF THE AMBULANCE FEE SCHEDULE"**

The IAFC supports the efforts of CMS to eliminate the requirement for annual review of the Conversion Factor (CF). It is our belief that the current CFs, created through the consensus process involving all of the NRC participants, are an accurate reflection of the various cost differences between the various levels of transport service.

5. **Comments on Hospital-to-Hospital Ambulance Service – Emergency Response "EMERGRENCY RESPONSE"**

The IAFC is concerned with the unilateral change being made by CMS to the definition of what constitutes an "emergency" response. The definition of an emergency response was determined by a consensus of all of the parties involved in the NRC. This consensus was reflected in the Consensus Committee Statement signed in February 2000, of which HCFA (now CMS) was signatory. It is the opinion of the IAFC that the previously agreed upon definition of emergency response needs to be maintained until the same parties involved in the original NRC process can be brought back together as a group to once again come to consensus on the proposed changes.

Additionally, the IAFC disagrees with the statement in the Proposed Rule that an emergency response payment is not warranted in many of the hospital-to-hospital transports. Fire Departments throughout the United States respond to hospitals on a regular basis to assist with the transport of critically ill or injured patients from the original facility to another, more capable, facility. In many cases, the request for transport comes into the Fire Department via the 911 system. However, regardless of the method of notification, on-duty EMS units take steps to immediately respond to the request for service. **These units should be reimbursed for all of these transports at the appropriate emergency response level.** These are not scheduled or non-emergency transports and the individual Medicare Carriers should not be given the latitude to reimburse the transports at any level other than the Emergency Response level of service. Whether our unit arrives at the hospital and immediately transports the patient or is asked to wait while the patient is stabilized is immaterial to the fact that the unit providing the service is an emergency response unit and responded to the facility immediately upon the request of the hospital. Based on our previous experience with some of the Medicare Carriers, it is our opinion that the language and intent of the Proposed Rule will create a situation where the Carriers can deny or downgrade the reimbursement at will and then require extensive documentation to support an obvious position. It is once again our concern that while CMS might be of the

opinion that reimbursement for these transports at the Emergency Response level will ultimately be won on appeal, it is the opinion of the IAFC that CMS needs to take measures beforehand to ensure that these types of claims are not denied in the first place.

6. Summary/Conclusion

Thank you for considering the International Association of Fire Chiefs comments on the Proposed Rule. As was outlined above, the IAFC is concerned with many of the changes identified in this Proposed Rule. It appears that over the last several years CMS has attempted to chip away at some of the fundamental consensus agreements reached between the NRC parties during the Negotiated Rulemaking process of 1999 and 2000. These agreements were reflected in the Consensus Committee Statement signed in February 2000, of which HCFA (now CMS) was signatory. It is the opinion of the IAFC that the previously agreed upon consensus agreements, including the wording of critical definitions, need to be maintained until the same parties involved in the original NRC process can be brought back together as a group to once again come to consensus on the proposed changes.

The IAFC respectfully requests that CMS move forward with holding a national meeting consisting of the agencies, and if possible, the individuals who were involved with the NRC process. It is the impression of many of the NRC participants that HCFA had intended to reconstitute the NRC as an advisory body as soon as the AFS was published as a Final Rule. This impression was formed over the period of time the NRC process was unfolding, as well as in subsequent conversations with the HCFA/CMS representatives while the Proposed Rule and Final Rule were being developed.

Should members of the CMS staff have questions regarding our comments or would like to meet with the IAFC and discuss them in person, please contact either Jack Krakeel, Public Safety Director for Fayette County (GA) at 770-461-1321 Ext. 5169 or Peter Lawrence, Battalion Chief for the Oceanside (CA) Fire Department at 760-435-4262.

Sincerely,

William D Killen

Chief William D. Killen, CFO
IAFC President

Jefferson Township

P. O. Box 188, Cassopolis, MI 49031
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July 15, 2006

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1317-P
P. O. Box 8017
Baltimore, MD 21244-8017

Re: CMS-1317P; Medicare Program; Revisions to the Payment Policies of Ambulance Services under the Fee Schedule for Ambulance Services

To Whom It May Concern:

We are commenting on the proposed rule change that would change the classification method for determining rural areas and payment to ambulance services. Under the proposed rule our ambulance service area would be changed from rural to urban. Our township population as of the 2000 Census is 2,401. The largest town in our county has a population of 6,147. Such a classification is not logical and will be burdensome on our taxpayers as we already need to subsidize our ambulance service so that we can have an ambulance near our community.

We urge your reconsideration of this proposed rule, and that CMS would further their efforts to recognize the cost of providing ambulance service to rural communities like ours.

Sincerely,

Jeffrey A. Carmen,
Supervisor

Leroy McNeary,
Clerk

Lotte Kirstein,
Treasurer

Dean Hass,
Trustee

Keith Kirkdorfer,
Trustee

JAC:sk

CLERK
Debra Dewey-Perry
203 Scribner, P.O. Box # 705
Delton, MI 49046

TREASURER
Judith E Wooer
10410 Cedar Creek Rd.
Delton, MI 49046

BARRY TOWNSHIP BOARD

BARRY COUNTY, MICHIGAN
P.O. Box 705, Delton, MI 49046 * (269) 623-5171 Fax 623-8171

TRUSTEE
Roger TurnerJr.
15283 Marshfield Rd.
Hickory Corners, Mi 49060

TRUSTEE
Wesley Kahler
150 E Orchard St
Delton, MI 49046

July 12, 2006

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1317-P
P.O. Box 8017
Baltimore, Maryland 21244-8017

Re: CMS-1317-P; Medicare Program; Revisions to the Payment Policies of Ambulance Services under the Fee Schedule for Ambulance Services

We are commenting on the proposed rule change that would change the classification method for determining rural areas and payment to ambulance services. Under the proposed rule our ambulance service area would be changed from rural to urban. The population for our entire township is 3,489 according to the 2000 census.. The largest town in our county has a population of 7,100. Changing our counties status away from rural is not logical and will make it more difficult for the communities in our township to be able to have adequate ambulance service.

We urge your reconsideration of this proposed rule. CMS should be looking at ways to increase Medicare payments to areas such as ours, not further reducing payments!

Sincererly,
Barry Township Clerk

10

BARRY COUNTY

Michael C. Brown
County Administrator

220 W. State St., Hastings, MI 49058
Ph. (269) 945-1284 Fax (269) 948-4884

July 13, 2006

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1317-P
PO Box 8017
Baltimore, Maryland 21244-8017

Re: CMS-1317-P; Medicare Program; Revisions to the Payment Policies of Ambulance Services Under the Fee Schedule for Ambulance Services

To Whom it May Concern:

I am commenting on the proposed rule change that would change the classification method for determining rural areas and payments to ambulance services. Under the proposed rule change Barry County's ambulance service area would be changed from rural to urban. The population of Barry County is only 59,371 according to the 2004 census estimates. The only incorporated City within Barry County, the City of Hastings, has a population of only 7,095.

I urge you to reconsider this proposed rule change. Changing Barry County's status from rural to urban will have a negative effect of reducing the ambulance services currently being provided to the citizens of Barry County.

Sincerely,

Michael C. Brown
County Administrator

Cc: Barry County Commissioners

Jack Dillon
Larry DeLong
Randy Payne

WASHINGTON COUNTY
BOARD OF SUPERVISORS

PO BOX 889
WASHINGTON, IOWA 52353

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FAX: (319) 653-7780

July 13, 2006

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1317-P
P.O. Box 8017
Baltimore, Maryland 21244-8017

To Whom It May Concern:

It has come to the attention of the Washington County Board of Supervisors, of your proposed rule entitled "Medicare Program; Revisions to the Payment Policies of Ambulance Services under the Fee Schedule for Ambulance Services." As the Board of Supervisors of Washington County, Iowa, we disagree with the proposed rule in making Washington County a metropolitan county.

Our ambulance service is already under enormous financial stress due to reduced Medicare reimbursement and increase operational cost. Such as, increased fuel cost that seem to increase daily; and the increase of operation for training and purchasing equipment for terrorist training that the federal government has mandated and the list could go on.

The rates under the Medicare ambulance fee schedule are 27% below the national average cost, of providing ambulance service to Medicare patients; with the cost difference even greater for low volume rural provider like our ambulance service in Washington County. Our service transports around 1,150 patients a year and Medicare patients account for approximately 50% of our call volume for our service. With this cut in the rural bonus for mileage, Washington County is looking at a decrease of $36,750.48 in payment from Medicare per year. This cut will need to be made up by an increase in county subsidy and increase in rates to other providers that do not have Medicare. With current budgets, this will be hard on the local community to make up such a large amount of funds, without a possible tax increase to support our ambulance service or make the hard decision of cutting ambulance services to the citizens of Washington County.

Washington County has a population of 19,600 and is 556 square miles in area. Washington County is a farming community, with the largest city being Washington, with a population of around 7,000. We have seven other smaller incorporated cities in the county: Kalona 2,300, Wellman 1,400, Riverside 928, Brighton 687, Ainsworth 524, Crawfordsville 295, and West Chester 159, the rest of the population lives in unincorporated areas of the county. As you can see by our towns and population, Washington County is rural. We would like you to look into how you make one county rural and not other county, there are several counties in Iowa that are much larger than Washington County that are still rural.

The Washington County Board of Supervisors would like you to reconsider switching Washington County from Metropolitan County to Rural County for Medicare payment. We would like you to look into other formulas on how counties are made rural or metropolitan; there has to be a better way of doing this, than what you are now considering that is fair and equable to everyone. We would invite you to contact us on this rule change or come to Washington County and see for yourself how rural this county is.

Sincerely,

Jack Dillon
Chairperson

Cc: Senator Charles Grassley
Senator Tom Harkins
Representative Jim Leach

PENN TOWNSHIP

12 July 2006

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1317-P
P.O. Box 8017
Baltimore, Maryland 21244-8017

Subject: CMS-1317-P; Medicare Program; Revisions to the Payment Policies of Ambulance Services under the Fee Schedule for Ambulance Services

Gentlemen and Ladies:

We write this letter to comment on the proposed rule revision which would change the classification method for determining rural areas and payment to ambulance services. Under the proposed rule our central Cass County Michigan ambulance service area would be changed from rural to urban. Our Penn Twp. Population is 1902 as of the 2000 Census...a loss of 142 people since 1980. Our ambulance service area actually consists of four combined townships which comprise 144 square miles in the center of Cass County. None are urban:

	2000 Population
LaGrange Twp.	3340
Calvin Twp.	2041
Jefferson Twp.	2401
Penn Twp.	1902

An urban classification for Cass County is not logical or factual and will fall as a burden on our taxpayers who are already required to subsidize our ambulance service so that we can have timely ambulance response near our communities. We urge your reconsideration of this proposed rule change, and that CMS would further their efforts to recognize the cost of providing ambulance service to rural communities like ours.

By copies of this letter, Penn Township requests that our Governmental leaders, who are well acquainted with the rural character of Cass County, take action to help us maintain affordable ambulance service. This request was unanimously authorized by Penn Township Board Resolution dated 10 July 2006. Your help will be greatly appreciated.

Very truly yours,

John K. Gore
Penn Township Supervisor
20849 Decatur Street
Cassopolis, Michigan 49031
Tel 269 445 2048

13

JUL 19 2006

Pinellas County
EMS & FIRE ADMINISTRATION

July 7, 2006

Mark B. McClellan, MD, Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1317-P; Medicare Program; Revisions to the Payment Policies of Ambulance Services under the Fee Schedule for Ambulance Services

Dear Dr. McClellan:

Pinellas County Emergency Medical Services, DBA Sunstar, welcomes this opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) Proposed Rule entitled "*Medicare Program; Revisions to the Payment Policies of Ambulance Services under the Fee Schedule for Ambulance Services*" ("Proposed Rule") 71 Fed. Reg. 30358 (May 26, 2006). The EMS Authority oversees an EMS system that runs 165,000 EMS requests for emergency and non-emergency ambulance and First Responder services each year. In FY04/05, Sunstar paramedic ambulance service transported over 116,000 patients.

1. Background

Section 4531 (b) (2) of the Balanced Budget Act of 1997 (BBA) mandated the development of a fee schedule for the reimbursement of ambulance services. This fee schedule was to replace the existing system of reimbursing ambulance services based on the reasonable costs of a provider or the reasonable charges of a supplier. The fee schedule was designed to create a more uniform payment system under Medicare for ambulance services. The BBA further mandated that certain aspects of this ambulance fee schedule be developed through a Negotiated Rulemaking process in consultation with various national organizations representing individuals and entities which furnish and regulate ambulance services. Included in the charter of Negotiated Rulemaking Committee (NRM Committee) was the task of developing "*definitions for ambulance services that link payments to the types of services furnished.*"

We understand the AAA was selected to participate in the Negotiated Rulemaking process as a member of the NRM Committee on Medicare ambulance fee schedule. The Health Care Financing Administration (HCFA), now CMS, as well as other national organizations representing ambulance interests, was also a member of the NRM Committee.

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The Committee Statement, signed on February 14, 2000, set forth the agreements reached by all members of the NRM Committee with respect to issues addressed in the proposed rule establishing the ambulance fee schedule. The Department of Health and Human Services, through HCFA, agreed to use this Committee Statement, to the maximum extent possible consistent with its legal obligations, as the basis for its Proposed Rule implementing the ambulance fee schedule.

The proposed rule implementing the ambulance fee schedule was issued on September 12, 2000, and was followed by a final rule on February 27, 2002. The ambulance fee schedule was phased-in over a five-year period commencing April 1, 2002. While the final agreement does not contain all of the preferred definitions of the AAA, the AAA was willing to compromise on several issues in order for the negotiated rulemaking to succeed. All members of the committee, including HCFA (CMS), compromised. In the Proposed Rule of May 26, 2006, however, CMS, without adequate explanation, has reneged on its agreement and proposed definitions for "emergency response" and "SCT" that are different from what was agreed to by all NRM Committee members, all of whom compromised for the sake of a successful outcome to the process.

Consistent with the Committee Agreement signed by the members of the NRM Committee on February 14, 2000, the AAA and every other participating national organization honored their commitment to support the definitions developed by the Committee. We remind CMS of its obligation to do the same. The BBA explicitly mandated that the establishment of definitions for the various types of ambulance services be developed in conjunction with industry representatives as part of the negotiated rulemaking process. For CMS now to abandon the agreement with respect to these definitions flies in the face of the provision in the BBA requiring specifically that definitions be developed through the negotiated rulemaking process.

2. **Summary of Comments**

Pinellas County Emergency Medical Services, DBA Sunstar, strongly objects to the proposed changes to the definitions of "emergency response" and "specialty care transport (SCT)" that were adopted by the NRM Committee and subsequently incorporated into the Final Rule of January 22, 2002. CMS has not articulated any public policy interest or legal rationale that would require these changes. For that reason its departure from the express terms of the Committee Agreement is arbitrary and capricious and not in accord with law.

Regarding the revised geographic determinations for rural and urban, we commend CMS on adopting Rural Urban Commuting Areas (RUCAs) as part of the most recent Goldsmith modification for identifying rural areas within urban tracts. For the past few years, the AAA has been advocating for RUCAs to be adopted under the Medicare ambulance fee schedule as the sole determination for rural and urban areas. While using the updated Goldsmith modification and thus RUCAs as only a modifier falls short of this objective, it is at least a step in the right direction.

Prior to implementing the new OMB standards for Core-Based Statistical Areas (CBSAs) as the primary determination, we are recommending that CMS take several steps which include mitigating the financial impact on those providers adversely affected by the change and providing the agency an opportunity to review the findings of the pending GAO report. We are hopeful that the GAO will provide the information necessary to determine the most appropriate means for identifying urban and rural areas when it comes to providing ambulance services. Since ambulance services are unique as a health care provider in that they go to the patient to

provide care, we want to make sure that CMS adopts a system for designating rural areas that is truly applicable to our industry.

The following are our detailed comments on each provision of the Proposed Rule:

3. **Specialty Care Transport**

The current definition for Specialty Care Transport, found in 42 C.F.R. 414.605, is as follows:

> *Specialty care transport (SCT)* means interfacility transportation of a critically injured or ill beneficiary by a ground ambulance vehicle, including medically necessary supplies and services, at a level of service beyond the scope of the EMT–Paramedic. SCT is necessary when a beneficiary's condition requires ongoing care that must be furnished by one or more health professionals in an appropriate specialty area, for example, nursing, emergency medicine, respiratory care, cardiovascular care, or a paramedic with additional training.

The Proposed Rule would change the origin/destination requirement in the definition to allow a SCT transport to be billed only in the case of "hospital-to-hospital" ambulance transports. The definition of SCT currently applies to "interfacility" transports. According to the Proposed Rule, the clarification would not effect a substantive change in policy under the ambulance fee schedule, but rather is only intended to conform the regulation text to the current policy of CMS on SCT. We strongly disagree with this characterization of the proposed change. Every word of this definition was carefully negotiated, especially the fact that the definition would apply to all types of interfacility transports involving specialty care. If current policy is to apply it only to transports between hospitals, that policy is contrary to the current regulation and totally inconsistent with the definition agreed to during the negotiated rulemaking process.

The Specialty Care Transport level of service was first recognized for a separate level of payment during the Negotiated Rulemaking process. At the time, the NRM Committee concluded that a higher level of payment was warranted where the ambulance service was called upon to provide a level of service beyond that of Advanced Life Support (ALS). This higher level of payment was intended to compensate ambulance services for the costs of providing certain medical equipment and highly trained personnel over and above basic state guidelines for ALS, as well as for the additional costs incurred in training paramedics beyond the basic paramedic curriculum.

Responsibility for creating a definition for SCT was tasked to the Medical Issues Workgroup of the NRM Committee. The Medical Issues Workgroup, in its report delivered December 7, 1999, ultimately recommended to the NRM Committee that SCT be defined as a: "*...a level of inter-facility transport service...*". There was no initial consensus that the SCT level of service be limited to inter-facility transports. The final recommendation was the result of a compromise among the members of the Workgroup. As late as August 1999, the working definition of the Workgroup for SCT included language that it *...might also include scene pick-up and transport of critically ill or injured patients by appropriately staffed specialty transport vehicles or aircraft.*"

The final language, i.e. defining SCT to be a form of "interfacility" transport, was the result of a compromise on this and other issues. Many committee members felt very strongly - and still do - that SCT should be paid when all of the other criteria are met, regardless of the origin and destination. Yet, largely to allay concerns by HCFA that the new level of service would be over-

billed, a compromise was reached to limit SCT to "interfacility" transports. HCFA expressly agreed to this definition and understood that it would include transports between a nursing facility and a hospital as well as between two hospitals.

CMS, without explanation, used the word "interhospital" in explaining the SCT definition in the preamble to the Proposed Rule published on September 12, 2000 rule. The proposed regulatory text itself, however, used the correct word, "interfacility". The problem with the explanatory language drew protests from members of the Negotiated Rulemaking Committee who had fought over the definition. The AAA pointed out that the Committee recommendation included transports between nursing facilities and hospitals and requested HCFA to correct the erroneous terminology in the preamble. As a result, CMS, which must have been aware of the discrepancy because of the comments it had received, retained the word "interfacility" in the definition of SCT in the regulations text in the final rule published on February 27, 2002. It remains that way in the regulation as it exists today. Therefore, it is disingenuous, at best, for CMS to say that it is making a clarifying rather substantive change. 1/

Moreover, other than stating that it is conforming its definition of SCT to its current policy, CMS has not articulated *any* reason why it should adopt such a policy. The Administrative Procedure Act requires an agency to publish a statement of the basis and purpose of any rule it adopts. CMS has failed to articulate a reason in this case, nor could it, for there is simply no good reason for limiting SCT to inter-hospital trips. The transport of a critically ill or injured beneficiary requires the same level of crew training, equipment and supplies regardless of whether that trip originated at a hospital or a nursing home. There are many patients in nursing homes who cannot be transported safely without the additional crew and/or equipment provided by SCT. CMS has not explained why its "current policy" should deny the appropriate level of care to these patients. In addition, restricting SCT to inter-hospital transports would also have the unintended effects of discouraging ambulance services from acquiring the necessary equipment and providing additional training for their paramedics or employing highly trained specialists and clinicians to provide appropriate transports for such patients.

If any clarification were needed to the definition of SCT, it would be to provide better guidance to the Carriers and intermediaries as to the medical conditions of patients warranting SCT. SCT requirements are usually set via medical protocols established on a local and/or state level. Because of this fact, the NRM Committee developed the definition of SCT to default to local requirements rather than attempt to set any type of national standard for when SCT level care would be appropriate or should be required for any type of patient. This is consistent with the general rule followed by the Committee, reflecting Medicare policy for all types of services, of deferring to state and/or local standards of practice on purely medical matters.

Unfortunately, some Carriers are interpreting the current definition of SCT in a manner inconsistent with local protocols. In particular, some carriers may be using a definition of "critically ill or injured" that may not correspond with local protocols. For example, while local standards and protocols may require a SCT level of care to transport a stable but ventilator-dependent patient (i.e., one who would be in dire condition if not for the apparatus on which he or she is dependent), the carrier may determine that because the patient is currently stable, he

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1/ As recently as 2005, when the issue of whether SCT coverage required interfacility vs. inter-hospital transports was brought up in Region V, CMS instructed a contractor (WPS) to pay claims at the SCT level for transports between skilled nursing homes and hospitals. See Medicare Part B Communiqué, Wisconsin Physicians Service Insurance Corp., June 2005, p.8. Also, this instruction was stated orally by CMS officials on several occasions over the past two years on the Ambulance Open Door Forum Calls.

or she is not "critically ill", and therefore the transport is downgraded. As a result, providers are required by local and state level medical protocols to provide SCT level care for patients but carriers are downgrading the transport to either ALS and even in some cases BLS as they decide individually in their opinions when SCT level care should be required. We believe carriers should refer to local requirements as to when SCT level care is required rather than decide on their own whether or not SCT is appropriate for any given patient. This was the intent of the NRM Committee when it developed the definition of SCT.

Therefore, we recommend that the definition of SCT be clarified by adding ", according to applicable local and/or state standards of practice," after the words "SCT care is necessary when a beneficiary's condition". This change would be consistent with the original intent of the NRM Committee as well as with general Medicare policy of deferring to local standards of medical practice. CMS should continue to monitor this issue to determine whether local standard are sufficiently well-developed to provide adequate guidance to the carriers or whether a national standard should be developed that would require an additional modification of the current definition of SCT.

Another clarification needed to the definition of SCT is that such transport is billable whether or not the specially trained personnel onboard the ambulance actually have to alter or activate, rather than monitor, the equipment required in an SCT transport. Some Carriers are claiming that unless specialty personnel actually have to alter equipment settings or otherwise manipulate equipment used during a transport, simply having medical teams on board with added certification that are clinically capable to monitor the equipment does not constitute the need for SCT level care. For example, ventilator dependent patients in many areas require personnel with specific training to know what to do if intervention is required. These Carriers are claiming that unless this intervention is actually required during the transport, the SCT level care was not required. So, if the personnel on board with additional training are there to monitor the patient during the transport, unless he/she actually has to intervene if something goes wrong, the transport is downgraded to an ALS level – and in some cases – a BLS level transport. This was also never the intent of the Committee in developing the SCT level transport during NRM.

CMS adopted a more enlightened and appropriate policy in the fee schedule of paying for ambulance services based in part on the cost of being ready to provide that service. That should apply to SCT level care as well. Otherwise, ambulance services are encouraged to provide unnecessary services to SCT patients who, fortunately, are transported without incident, or, conversely, to transport critically ill patients without the appropriate personnel and equipment onboard. Therefore, we recommend that the definition of SCT also be clarified by adding the words ", including the monitoring of specialty equipment required by the patient," after the words "requires ongoing care".

In summary, the CMS proposed revision of the definition of "specialty care transport" is not a simple clarification of existing policy, as CMS claims, but rather is fundamentally inconsistent with the definition agreed to by the NRM Committee. Nor has CMS proffered any basis or purpose for this change, as required by the Administrative Procedure Act. Accordingly, it would be arbitrary and capricious for CMS to implement this proposed change, which would be harmful to the best interests of patients and unfair to patients and ambulance providers alike.

4. Emergency Response

During the negotiated rulemaking process, it was agreed that a higher level of payment would be assigned for an emergency response. As the Committee Statement made clear, this higher level of payment was justified in order to compensate the ambulance service for the additional costs incurred in maintaining the readiness to undertake an immediate response. The February 27, 2002 Final Rule essentially adopted the recommendations of the NRM Committee. However, the February 27, 2002 Final Rule added a further requirement that the ambulance be dispatched pursuant to a 911 call or the equivalent in areas without a 911 system. CMS subsequently agreed that an emergency response could be the result of calls that are received on the private line of an ambulance entity.

The Proposed Rule would change the definition of "emergency response" to:

> "Emergency response means that an ambulance entity (1) maintains readiness to respond to urgent calls at the BLS or ALS1 level of service, and (2) responds immediately at the BLS or ALS1 level of service to 911 calls, the equivalent in areas without a 911 call system or radio calls within a hospital system when the ambulance entity is owned and operated by the hospital"

We fail to understand either the purpose of the proposed change, as set forth in the preamble to the Proposed Rule, or the actual effect of the proposed change to the text of the regulation. As with the proposed change to the definition of SCT, discussed above, the failure of CMS to set forth an adequate basis and purpose for a change to a rule that was mandated to be developed through negotiated rulemaking is arbitrary and capricious. As with the SCT definition, few, if any, provisions of the fee schedule negotiated rule provoked as much debate and hard fought compromise as did the definition of "emergency response." For CMS now to abandon that definition and unilaterally come up with inadequately explained substantive changes amounts to an arbitrary disregard of the negotiated rulemaking process and the good faith efforts and compromises of the participants in that process.

The Proposed Rule states that this revision is intended to clarify confusion over the present definition, and to ensure that the higher level of payment for an emergency response is limited to those situations in which an immediate response is truly warranted. We agree that a degree of confusion exists with respect to the present definition of "emergency response," particularly with respect to transports that originate at a hospital. However, the Proposed Rule does nothing to alleviate that confusion; it merely compounds it.

As discussed above, the higher level of payment for emergency transports is intended to compensate the ambulance service for the additional costs incurred in maintaining the readiness to respond immediately. The Committee Statement intended to draw no distinction as to the manner in which calls come in. The key is whether an immediate response was needed. Additionally, no distinction was felt to be appropriate as to the ownership of the vehicle that responds. This very issue was discussed in great detail by the NRM Committee. Whether the call came in to a hospital owned, privately owned, publicly owned or volunteer organization, the issue is the cost of readiness - not ownership.

The proposed definition would permit an ambulance service to bill for an emergency response whenever it responds immediately to radio calls within a hospital system when the ambulance service is "owned and operated by the hospital." We agree with CMS that a 911 call should not

be required. However, we would not limit this to ambulance services owned and operated by hospitals. It is common for calls to be received on private lines to arrange for transports, including emergency transports. The manner in which the call is received (911, 311, radio call, private line, computer, etc.) should not matter for purposes of determining an emergency response. Technology dictates how these calls are most effectively made and the technology is constantly changing.

The discussion contained in the preamble of the Proposed Rule indicates that the intent of the rule change is to preclude billing for an emergency response in most cases when a beneficiary is transported from the emergency department of one hospital to the emergency department of a second hospital. We agree that an emergency response often would not be justified in situations where the beneficiary was stabilized at the first hospital prior to transport and no emergency condition exists. However, we do not understand how the Proposed Rule would accomplish the objective, nor can we agree that an emergency response would never be justified for ED to ED transports.

The Proposed Rule adds a reference to "radio calls within a hospital system when the ambulance entity is owned and operated by the hospital" to the types of dispatches permitted. Additionally, the proposal eliminates the requirement in the current regulation that "the ambulance entity begins as quickly as possible to take steps to respond to the call." How those two changes address the issue of hospital ambulances billing inappropriately for hospital-to-hospital transports is not explained in the Proposed Rule; nor is it apparent.

The condition of the beneficiary, *as reported to the ambulance dispatcher,* not actual or eventual condition, should determine whether an emergency response is warranted. That is the effect of the current rule and we believe it should not be changed. The example in the Proposed Rule seemingly would impose a requirement that the ambulance service determine the actual condition of the beneficiary at the time of dispatch (i.e. stabilized vs. unstabilized). Such an inquiry would be inconsistent with the purposes underlying the higher level of payment for an emergency response. As stated in the February 27, 2002 Final Rule "the purpose of the higher payment for emergency response is to recognize the additional costs required in order to be prepared to respond immediately to a call.....without regard to the condition of the beneficiary."

Finally, no distinction should be made as to where the vehicle is located at the time it is dispatched or the point of pick-up of the patient. The Proposed Rule suggests that an ambulance that is stationed at a hospital could not meet the requirement for an emergency response. However, consider, for example, an inpatient at a psychiatric, rehabilitation, or long-term care hospital that goes into cardiac arrest. In this instance, an emergency response would clearly be justified. Another example is a life threatening emergency brought to an emergency department, but, whether stabilized or not, emergency treatment is needed that the hospital ED cannot provide (e.g. on diversion, physician specialist not available, equipment not available, etc.). In these cases, an emergency response to take the patient to another hospital ED is clearly warranted. The mere fact that the ambulance happens to be stationed at the hospital does not alter the nature of the response. Nor does it relieve the ambulance entity of the cost of being prepared to respond immediately to such calls, the costs of which CMS has clearly indicated justify payment at the emergency level of services.

We do not believe the Proposed Rule would dispel any confusion that may exist with respect to emergency billing for hospital-to-hospital transports and we urge CMS to abandon this approach. The result of this regulation will only be greater confusion. We suggest that, if the case can be made for the need for clarification, CMS call the parties to the negotiated

rulemaking together to obtain their input regarding the nature of the problem and possible regulatory or interpretive solutions thereto. Anything short of that would be inconsistent with the obligations of CMS under the Committee Agreement, and would likely lead to further confusion.

5. Conversion Factor/Air Ambulance Rates

Pinellas County Emergency Medical Services, DBA Sunstar, has no objection at this time to eliminating the annual reviews of the conversion factor and air ambulance data.

6. Conclusion

Thank you for your consideration of these comments, Pinellas County Emergency Medical Services, DBA Sunstar, remains committed to working with CMS toward the establishment of a fair and efficient ambulance fee schedule. To that end, we would be happy to provide any additional information that you or your staff may require. We are also prepared to meet with CMS at any time to discuss these comments in more detail.

If you or your staff should have any questions regarding our comments, please contact me at (727) 582-2089.

Sincerely,

Conrad T. Kearns, MBA, Paramedic
Director, Pinellas County EMS/Fire Administration

f/users/emszc07/CMS comments amb definitions

The Georgia Association of Emergency Medical Services

GAEMS

" Dedicated to Quality Pre-Hospital Care"

Georgia Association of Emergency Medical Services, Inc.
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June 21, 2006

Mark B. McClellan, MD, PHD
Administrator
Centers for Medicare and Medicaid Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Ref: CMS-1317; Medicare Program; Revisions to the Payment Policies of Ambulance Services under the Fee Schedule for Ambulance Services

Dear Dr. McClellan:

The Georgia Association of Emergency Medical Services represents the EMS industry in our State. Our membership consists of EMS Directors, EMS personnel who provide direct care to patients, Medical Director's of Ambulance Services and EMS educators.

I have reviewed the letter from the American Ambulance Association written in regards to this subject. The GAEMS is in complete agreement with their position. For your convenience I have enclosed copies of their letter. I do however, feel it appropriate to expand on several issues.

SPECIALTY CARE TRANSPORT

In today's health care environment hospitals are encouraged to discharge patients as soon as possible to decrease medical costs. Many of these individuals go to long term care facilities, which do not meet the definition of a hospital. The care requirements for patient transportation, both in personnel and equipment, will remain the same. Your regulation may incur more cost to the system by causing EMS services to deny making these trips or long term care facilities refusing to accept patients they cannot arrange transportation for.

EMERGENCY RESPONSE

In the Federal Register you make the comment "...in most of these cases, the beneficiary must be stabilized prior to the transport". I take exception to this statement. In the early days of EMS we were taught not to transport a patient from the scene of an accident until they were "properly treated and stabilized". Today, with a better understanding of how people die from trauma, we realized we "stabilized" many people to death. It is my belief that most of these transports do indeed meet the CMS definition for emergency. The growing base of knowledge in trauma care, stroke care and cardiac care now are proving the importance of immediate transport to a specialty center for the proper treatment of these patients. For CMS to say that these citizens do not require an "emergency response" is unfortunate and inaccurate.

Many of the ambulance services in Georgia are operated by hospitals. Some of these do so as a distinct entity of the hospital and some do this in a contractual arrangement with local government to handle 911 calls. If these services operate in Georgia as a 911 provider then they must, by State law, be immediately available to respond. For CMS to deny these ambulance providers the ability to bill for "emergency care" would be a great disservice to the citizens they serve.

Thank you for the opportunity to respond to your proposed rule.

Sincerely,

Courtney L. Terwilliger
Chairman

AMERICAN AMBULANCE ASSOCIATION

American Ambulance Association
8201 Greensboro Drive, Suite 300
McLean, Virginia 22102
Phone: (703) 610-9018
Fax: (703) 610-9005
Website: www.the-aaa.org

"The American Ambulance Association promotes health care policies that ensure excellence in the ambulance service industry and provides research, education, and communications programs to enable members to effectively address the needs of the communities they serve."

June 28, 2006

Mark B. McClellan, MD, Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1317-P; Medicare Program; Revisions to the Payment Policies of Ambulance Services under the Fee Schedule for Ambulance Services

Dear Dr. McClellan:

The American Ambulance Association (AAA) welcomes this opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) Proposed Rule entitled "*Medicare Program; Revisions to the Payment Policies of Ambulance Services under the Fee Schedule for Ambulance Services*" ("Proposed Rule") 71 Fed. Reg. 30358 (May 26, 2006). The American Ambulance Association is the primary trade association representing ambulance service providers that participate in serving communities with emergency and non-emergency ambulance services. The AAA is composed of more than 600 ambulance operations and has members in every state. AAA members include private, public and fire and hospital-based providers covering urban, suburban and rural areas. The AAA was formed in 1979 in response to the need for improvements in medical transportation and emergency medical services. The Association serves as a voice and clearinghouse for ambulance service providers who view pre-hospital care not only as a public service but also as an essential part of the total public heath care system. The comments submitted herein are on behalf of our members, most of which would be adversely affected by one or more of the proposed changes to definitions.

1. Background

Section 4531 (b) (2) of the Balanced Budget Act of 1997 (BBA) mandated the development of a fee schedule for the reimbursement of ambulance services. This fee schedule was to replace the existing system of reimbursing ambulance services based on the reasonable costs of a provider or the reasonable charges of a supplier. The fee schedule was designed to create a more uniform payment system under Medicare for ambulance services. The BBA further mandated that certain aspects of this ambulance fee schedule be developed through a Negotiated Rulemaking process in consultation with various national

organizations representing individuals and entities which furnish and regulate ambulance services. Included in the charter of Negotiated Rulemaking Committee (NRM Committee) was the task of developing "*definitions for ambulance services that link payments to the types of services furnished.*"

The AAA was selected to participate in the Negotiated Rulemaking process as a member of the NRM Committee on Medicare ambulance fee schedule. The Health Care Financing Administration (HCFA), now CMS, as well as other national organizations representing ambulance interests, was also a member of the NRM Committee.

The Committee Statement (copy enclosed), signed on February 14, 2000, set forth the agreements reached by all members of the NRM Committee with respect to issues addressed in the proposed rule establishing the ambulance fee schedule. The Department of Health and Human Services, through HCFA, agreed to use this Committee Statement, to the maximum extent possible consistent with its legal obligations, as the basis for its Proposed Rule implementing the ambulance fee schedule.

The proposed rule implementing the ambulance fee schedule was issued on September 12, 2000, and was followed by a final rule on February 27, 2002. The ambulance fee schedule was phased-in over a five-year period commencing April 1, 2002. While the final agreement does not contain all of the preferred definitions of the AAA, the AAA was willing to compromise on several issues in order for the negotiated rulemaking to succeed. All members of the committee, including HCFA (CMS), compromised. In the Proposed Rule of May 26, 2006, however, CMS, without adequate explanation, has reneged on its agreement and proposed definitions for "emergency response" and "SCT" that are different from what was agreed to by all NRM Committee members, all of whom compromised for the sake of a successful outcome to the process.

Consistent with the Committee Agreement signed by the members of the NRM Committee on February 14, 2000, the AAA and every other participating national organization honored their commitment to support the definitions developed by the Committee. The AAA reminds CMS of its obligation to do the same. The BBA explicitly mandated that the establishment of definitions for the various types of ambulance services be developed in conjunction with industry representatives as part of the negotiated rulemaking process. For CMS now to abandon the agreement with respect to these definitions flies in the face of the provision in the BBA requiring specifically that definitions be developed through the negotiated rulemaking process.

2. Summary of Comments

The AAA strongly objects to the proposed changes to the definitions of "emergency response" and "specialty care transport (SCT)" that were adopted by the NRM Committee and subsequently incorporated into the Final Rule of January 22, 2002. CMS has not articulated any public policy interest or legal rationale that would require these changes. For that reason its departure from the express terms of the Committee Agreement is arbitrary and capricious and not in accord with law.

Regarding the revised geographic determinations for rural and urban, we commend CMS on adopting Rural Urban Commuting Areas (RUCAs) as part of the most recent Goldsmith modification for identifying rural areas within urban tracts. For the past few years, the AAA has been advocating for RUCAs to be adopted under the Medicare ambulance fee schedule as the sole determination for rural and urban areas. While using the updated Goldsmith modification and thus RUCAs as only a modifier falls short of this objective, it is at least a step in the right direction.

Prior to implementing the new OMB standards for Core-Based Statistical Areas (CBSAs) as the primary determination, we are recommending that CMS take several steps which include mitigating the financial impact on those providers adversely affected by the change and providing the agency an opportunity to review the findings of the pending GAO report. We are hopeful that the GAO will provide the information necessary to determine the most appropriate means for identifying urban and rural areas when it comes to providing ambulance services. Since ambulance services are unique as a health care provider in that they go to the patient to provide care, we want to make sure that CMS adopts a system for designating rural areas that is truly applicable to our industry.

The following are our detailed comments on each provision of the Proposed Rule:

3. <u>Specialty Care Transport</u>

The current definition for Specialty Care Transport, found in 42 C.F.R. 414.605, is as follows:

> *Specialty care transport (SCT)* means interfacility transportation of a critically injured or ill beneficiary by a ground ambulance vehicle, including medically necessary supplies and services, at a level of service beyond the scope of the EMT–Paramedic. SCT is necessary when a beneficiary's condition requires ongoing care that must be furnished by one or more health professionals in an appropriate specialty area, for example, nursing, emergency medicine, respiratory care, cardiovascular care, or a paramedic with additional training.

The Proposed Rule would change the origin/destination requirement in the definition to allow a SCT transport to be billed only in the case of "hospital-to-hospital" ambulance transports. The definition of SCT currently applies to "interfacility" transports. According to the Proposed Rule, the clarification would not effect a substantive change in policy under the ambulance fee schedule, but rather is only intended to conform the regulation text to the current policy of CMS on SCT. We strongly disagree with this characterization of the proposed change. Every word of this definition was carefully negotiated, especially the fact that the definition would apply to all types of interfacility transports involving specialty care. If current policy is to apply it only to transports

between hospitals, that policy is contrary to the current regulation and totally inconsistent with the definition agreed to during the negotiated rulemaking process.

The Specialty Care Transport level of service was first recognized for a separate level of payment during the Negotiated Rulemaking process. At the time, the NRM Committee concluded that a higher level of payment was warranted where the ambulance service was called upon to provide a level of service beyond that of Advanced Life Support (ALS). This higher level of payment was intended to compensate ambulance services for the costs of providing certain medical equipment and highly trained personnel over and above basic state guidelines for ALS, as well as for the additional costs incurred in training paramedics beyond the basic paramedic curriculum.

Responsibility for creating a definition for SCT was tasked to the Medical Issues Workgroup of the NRM Committee. The Medical Issues Workgroup, in its report delivered December 7, 1999, ultimately recommended to the NRM Committee that SCT be defined as a: "*...a level of inter-facility transport service...*". There was no initial consensus that the SCT level of service be limited to inter-facility transports. The final recommendation was the result of a compromise among the members of the Workgroup. As late as August 1999, the working definition of the Workgroup for SCT included language that it *...might also include scene pick-up and transport of critically ill or injured patients by appropriately staffed specialty transport vehicles or aircraft.*"

The final language, i.e. defining SCT to be a form of "interfacility" transport, was the result of a compromise on this and other issues. Many committee members felt very strongly - and still do - that SCT should be paid when all of the other criteria are met, regardless of the origin and destination. Yet, largely to allay concerns by HCFA that the new level of service would be over-billed, a compromise was reached to limit SCT to "interfacility" transports. HCFA expressly agreed to this definition and understood that it would include transports between a nursing facility and a hospital as well as between two hospitals.

CMS, without explanation, used the word "interhospital" in explaining the SCT definition in the preamble to the Proposed Rule published on September 12, 2000 rule. The proposed regulatory text itself, however, used the correct word, "interfacility". The problem with the explanatory language drew protests from members of the Negotiated Rulemaking Committee who had fought over the definition. We pointed out that the Committee recommendation included transports between nursing facilities and hospitals and we requested HCFA to correct the erroneous terminology in the preamble. As a result, CMS, which must have been aware of the discrepancy because of the comments it had received, retained the word "interfacility" in the definition of SCT in the regulations text in the final rule published on February 27, 2002. It remains that way in the regulation as it exists today. Therefore, it is disingenuous, at best, for CMS to say that it is making a clarifying rather substantive change. 1/

1/ As recently as 2005, when the issue of whether SCT coverage required interfacility vs. inter-hospital transports was brought up in Region V, CMS instructed a contractor (WPS) to pay claims at the SCT level for transports between skilled nursing homes and hospitals. See Medicare Part B Communiqué, Wisconsin

Moreover, other than stating that it is conforming its definition of SCT to its current policy, CMS has not articulated *any* reason why it should adopt such a policy. The Administrative Procedure Act requires an agency to publish a statement of the basis and purpose of any rule it adopts. CMS has failed to articulate a reason in this case, nor could it, for there is simply no good reason for limiting SCT to inter-hospital trips. The transport of a critically ill or injured beneficiary requires the same level of crew training, equipment and supplies regardless of whether that trip originated at a hospital or a nursing home. There are many patients in nursing homes who cannot be transported safely without the additional crew and/or equipment provided by SCT. CMS has not explained why its "current policy" should deny the appropriate level of care to these patients. In addition, restricting SCT to inter-hospital transports would also have the unintended effects of discouraging ambulance services from acquiring the necessary equipment and providing additional training for their paramedics or employing highly trained specialists and clinicians to provide appropriate transports for such patients.

If any clarification were needed to the definition of SCT, it would be to provide better guidance to the Carriers and intermediaries as to the medical conditions of patients warranting SCT. SCT requirements are usually set via medical protocols established on a local and/or state level. Because of this fact, the NRM Committee developed the definition of SCT to default to local requirements rather than attempt to set any type of national standard for when SCT level care would be appropriate or should be required for any type of patient. This is consistent with the general rule followed by the Committee, reflecting Medicare policy for all types of services, of deferring to state and/or local standards of practice on purely medical matters.

Unfortunately, some Carriers are interpreting the current definition of SCT in a manner inconsistent with local protocols. In particular, some carriers may be using a definition of "critically ill or injured" that may not correspond with local protocols. For example, while local standards and protocols may require a SCT level of care to transport a stable but ventilator-dependent patient (i.e., one who would be in dire condition if not for the apparatus on which he or she is dependent), the carrier may determine that because the patient is currently stable, he or she is not "critically ill", and therefore the transport is downgraded. As a result, providers are required by local and state level medical protocols to provide SCT level care for patients but carriers are downgrading the transport to either ALS and even in some cases BLS as they decide individually in their opinions when SCT level care should be required. We believe carriers should refer to local requirements as to when SCT level care is required rather than decide on their own whether or not SCT is appropriate for any given patient. This was the intent of the NRM Committee when it developed the definition of SCT.

Therefore, we recommend that the definition of SCT be clarified by adding ", according to applicable local and/or state standards of practice," after the words "SCT care is necessary when a beneficiary's condition". This change would be consistent with the

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CMS adopted a more enlightened and appropriate policy in the fee schedule of paying for ambulance services based in part on the cost of being ready to provide that service. That should apply to SCT level care as well. Otherwise, ambulance services are encouraged to provide unnecessary services to SCT patients who, fortunately, are transported without incident, or, conversely, to transport critically ill patients without the appropriate personnel and equipment onboard. Therefore, we recommend that the definition of SCT also be clarified by adding the words ", including the monitoring of specialty equipment required by the patient," after the words "requires ongoing care".

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requirement that the ambulance be dispatched pursuant to a 911 call or the equivalent in areas without a 911 system. CMS subsequently agreed that an emergency response could be the result of calls that are received on the private line of an ambulance entity.

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We fail to understand either the purpose of the proposed change, as set forth in the preamble to the Proposed Rule, or the actual effect of the proposed change to the text of the regulation. As with the proposed change to the definition of SCT, discussed above, the failure of CMS to set forth an adequate basis and purpose for a change to a rule that was mandated to be developed through negotiated rulemaking is arbitrary and capricious. As with the SCT definition, few, if any, provisions of the fee schedule negotiated rule provoked as much debate and hard fought compromise as did the definition of "emergency response." For CMS now to abandon that definition and unilaterally come up with inadequately explained substantive changes amounts to an arbitrary disregard of the negotiated rulemaking process and the good faith efforts and compromises of the participants in that process.

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The Proposed Rule adds a reference to "radio calls within a hospital system when the ambulance entity is owned and operated by the hospital" to the types of dispatches permitted. Additionally, the proposal eliminates the requirement in the current regulation that "the ambulance entity begins as quickly as possible to take steps to respond to the call." How those two changes address the issue of hospital ambulances billing inappropriately for hospital-to-hospital transports is not explained in the Proposed Rule; nor is it apparent.

The condition of the beneficiary, *as reported to the ambulance dispatcher,* not actual or eventual condition, should determine whether an emergency response is warranted. That is the effect of the current rule and we believe it should not be changed. The example in the Proposed Rule seemingly would impose a requirement that the ambulance service determine the actual condition of the beneficiary at the time of dispatch (i.e. stabilized vs. unstabilized). Such an inquiry would be inconsistent with the purposes underlying the higher level of payment for an emergency response. As stated in the February 27, 2002 Final Rule "the purpose of the higher payment for emergency response is to recognize the additional costs required in order to be prepared to respond immediately to a call.....without regard to the condition of the beneficiary."

Finally, no distinction should be made as to where the vehicle is located at the time it is dispatched or the point of pick-up of the patient. The Proposed Rule suggests that an ambulance that is stationed at a hospital could not meet the requirement for an emergency response. However, consider, for example, an inpatient at a psychiatric, rehabilitation, or long-term care hospital that goes into cardiac arrest. In this instance, an emergency response would clearly be justified. Another example is a life threatening emergency brought to an emergency department, but, whether stabilized or not, emergency treatment is needed that the hospital ED cannot provide (e.g. on diversion, physician specialist not available, equipment not available, etc.). In these cases, an emergency response to take the patient to another hospital ED is clearly warranted. The mere fact that the ambulance happens to be stationed at the hospital does not alter the nature of the response. Nor does it

relieve the ambulance entity of the cost of being prepared to respond immediately to such calls, the costs of which CMS has clearly indicated justify payment at the emergency level of services.

We do not believe the Proposed Rule would dispel any confusion that may exist with respect to emergency billing for hospital-to-hospital transports and we urge CMS to abandon this approach. The result of this regulation will only be greater confusion. We suggest that, if the case can be made for the need for clarification, CMS call the parties to the negotiated rulemaking together to obtain their input regarding the nature of the problem and possible regulatory or interpretive solutions thereto. Anything short of that would be inconsistent with the obligations of CMS under the Committee Agreement, and would likely lead to further confusion.

5. **CBSAs-Revised OMB Metropolitan Area Definitions and RUCAs**

The AAA commends CMS for its decision to adopt Rural Urban Commuting Areas (RUCAs) as part of the most recent Goldsmith modification for identifying rural areas within urban tracts. We are also pleased that the Office of Management and Budget Core-Based Statistical Areas (CBSAs) standard identifies Micropolitan Statistical Areas as being non-urban. However, we are concerned about the immediate effect that the resulting reclassification of certain areas from rural to urban will have on providers of ambulance services in those areas.

The NRM Committee was concerned that the system that it developed for recognizing the additional cost of providing ambulance services in low-volume rural areas was imperfect at best. CMS vowed to continue to review the cost and demographic problems presented by this issue to improve the degree to which its payment system for ambulance services recognizes these additional costs. The Government Accountability Office (GAO) has also been asked by Congress to review this issue, and its report is expected to be issued in the near future. Finally, the concerns of Congress about the adequacy of ambulance payments was demonstrated by the enactment in the Medicare Modernization Act, P.L. 108-173 (MMA) through several provisions designed to provide temporary relief until the studies have been completed and a more reasonable system enacted (e.g., the adjustment for certain long trips, assistance for providers in low population density areas, and the two-percent increase in payment rates for rural areas).

Given the uncertainty surrounding the appropriate payment rate for rural ambulance services in general, we believe the implementation of these statistical area changes for those areas that would lose their rural designation should be tempered by the following steps:

1) Ambulance trips in rural areas that obtained some form of relief that was enacted in the MMA should continue to be treated in accordance with the terms of those provisions for the period specified by Congress, regardless of their new classification.

2) Ambulance services should be provided the same protections that CMS provided to hospitals adversely affected by the CBSA and RUCA changes in the Inpatient Hospital Final Rule for 2005. 2/ Specifically, any area (list of areas enclosed) that would lose its rural designation because of these changes should be protected by a three-year hold harmless to allow providers to adjust their budgets and business practices to the rate changes.

3) Although no formal reclassification process exists for ambulance providers, CMS should put in place a process by which providers could present data and other information justifying why particular areas should continue to be classified as rural. Because the urban/rural distinction for ambulances services is totally a creature of regulation, rather than statute, such a process would clearly be within the authority of CMS.

4) CMS should consider whether, in light of all the uncertainties discussed above, the adoption of the new OMB CBSA classification system should be postponed until after the GAO study has been completed and CMS and the Congress have had an opportunity to adopt any recommendation that are appropriate.

6. Conversion Factor/Air Ambulance Rates

The AAA has no objection at this time to eliminating the annual reviews of the conversion factor and air ambulance data.

7. Conclusion

Thank you for your consideration of these comments. The AAA remains committed to working with CMS toward the establishment of a fair and efficient ambulance fee schedule. To that end, we would be happy to provide any additional information that you or your staff may require. We are also prepared to meet with CMS at any time to discuss these comments in more detail. If it is determined that the NRM Committee should be consulted to resolve any of the issues raised by the Proposed Rule, we look forward to the opportunity to participate in that process.

If you or your staff should have any questions regarding our comments, please contact myself or Tristan North, AAA Vice President of Government Affairs, at 703-610-9018.

Sincerely,

Robert L. Garner
President

enclosures

2/ 69 Fed. Reg. 48916, 49032 (Aug. 11, 2004).

F-M Ambulance Service
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July 17, 2006

Mark B. McClellan, MD, Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1317-P; Medicare Program; Revisions to the Payment Policies of Ambulance Services under the Fee Schedule for Ambulance Services

Dear Dr. McClellan:

F-M Ambulance Service welcomes the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) Proposed Rule entitled "*Medicare Program; Revisions to the Payment Policies of Ambulance Services under the Fee Schedule for Ambulance Services*" ("Proposed Rule") 71 Fed. Reg. 30358 (May 26, 2006). F-M Ambulance Service provides critical ambulance services to the Medicare beneficiaries and residents of Fargo and Moorhead. We encourage you to give serious consideration to the comments outlined in our letter.

Summary of Comments

Our organization strongly objects to the proposed changes to the definitions of "emergency response" and "specialty care transport (SCT)" that were adopted by the Negotiated Rulemaking Committee (NRM Committee) for the Medicare Ambulance Fee Schedule and subsequently incorporated into the Final Rule of January 22, 2002. CMS has not articulated any public policy interest or legal rationale that would require these changes. These changes would be detrimental not only to our operation but the Medicare beneficiaries we serve.

Regarding the revised geographic determinations for rural and urban, we commend CMS on adopting Rural Urban Commuting Areas (RUCAs) as part of the most recent Goldsmith modification for identifying rural areas within urban tracts. As a member of the American Ambulance Association, we have been supportive of using RUCAs as the sole geographical determination for ambulance services. While using the updated Goldsmith modification and thus RUCAs as only a modifier falls short of this objective, it is at least a step in the right direction.

ASSOCIATION OF AIR MEDICAL SERVICES

July 21, 2006

The Honorable Mark McClellan
Administrator
Center for Medicare and Medicaid Services
Hubert Humphrey Building, Room 314-G
200 Independence Ave., SW
Washington, DC 20201

RE: Comments to CMS-1317-P; Revisions to the Payment Policies of Ambulance Services under the Fee Schedule for Ambulance Services

Dear Dr. McClellan:

The Association of Air Medical Services (AAMS) would like to begin by thanking the Centers for Medicare and Medicaid Services (CMS) for the opportunity to comment on the recently published Proposed Rule entitled "Medicare Program; Revisions to the Payment Policies of Ambulance Services under the Fee Schedule for Ambulance Services" 71 Federal Register 30358 (May 26, 2006). While AAMS agrees with some of the proposals contained in the Proposed Rule, we have some significant concerns regarding the completeness of the Proposed Rule, and believe that there was not sufficient information contained in the proposal to allow AAMS, or our many members of the air ambulance community, to fully comment on the proposal. Therefore, we believe that the questions raised by the comments below should be answered in the form of another "Proposed Rule" prior to moving forward with a final rule.

AAMS is the sole trade association representing air medical and critical care ground providers across the country, and as such has a unique perspective on issues related to emergency response and the provision of EMS services. Our member rolls include over 300 services, comprised of non-profit, for-profit and government operators that conduct over 500,000 patient transports each year using approximately 750 rotor-wing (or helicopter) and 180 fixed-wing (or airplane) air ambulances plus 200 critical care ground ambulances nationwide.

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Overview of Comments

While it is understandable to make changes to urban and rural area designations as the demographics of our country change, AAMS understands that narrowing the definition of rural areas will increase the number of urban areas, thereby greatly decreasing the amount of reimbursement for air ambulance operations in those areas. Operating costs in air medical operations have increased far faster than inflation since the Fee Schedule was developed pre 9-11 due to rising fuel,

insurance and medical supply costs, as well as personnel shortages. Assuring that aircraft are safely operated and maintained is also an increasingly costly endeavor as ambulance operations strive for the highest levels of safety. By narrowing the definition of rural areas and thereby decreasing the amount of reimbursement to air medical operations by a significant amount, this proposed rule would make operating in previously defined rural areas, where distances require air ambulance services the most, almost fiscally impossible.

CBSAs-Revised OMB Micropolitan Area Definitions

While we understand the need to update the rural county definitions, and concur that Micropolitan Areas should be considered rural for ambulance payment, we believe that the this change of definition will have a significant impact on many ambulance providers located in what have historically been rural areas that now may be reclassified as urban. AAMS would like to recommend a multi-year phase-in period to allow providers to make the necessary adjustments in their operations.

Further, these definitions will adversely affect air ambulances more than ground ambulances because of the inherently larger rural modifier. As we will discuss below under the "Regulatory Impact" section, we believe the air ambulance rates should be adjusted upwards in an effort to make certain that these adjustments result in a budget neutral proposal.

We would also like clarification on how the Zip Code list is developed and administered. We understand that CMS regularly issues ZIP Code updates that designate some areas as "rural" and others as "urban". What is the specific methodology used to cross-walk the county designations to Zip Codes, given that ZIP Codes often do not follow county lines? For example, if a particular ZIP Code encompasses two counties, with 80% of it in an Urban county, and 20% in a Rural county, is that ZIP Code assigned a "rural" or "urban" designation? In this example, if the ZIP Code were to be designated as "urban," yet the patient was picked up in the part of the ZIP Code that was in the rural county, would ambulance providers still not be eligible for the rural payment? AAMS strongly recommends that CMS create some mechanism to ensure that, especially in large rural counties, ground and air ambulance are properly reimbursed according to the type of area in which the patient is located.

Rural-Urban Commuting Area Codes (RUCA's)

The Proposed Rule erroneously refers to the Rural-Urban Commuting Area Codes (RUCA) as an "update to the Goldsmith modification." While there may be some similarities between Goldsmith and RUCA, RUCA was developed collaboratively by the Health Resources and Service Administration's (HRSA's) Office of Rural Health Policy (ORHP), the Department of Agriculture's Economic Research Service (ERS) , and the WWAMI Rural Health Research Center (RHRC) under a Federal grant to develop an entirely new Census tract-based classification system. We do not believe that either the original RUCA grant, or the resulting final report on RUCA, ever referred to RUCA as an "Update to the Goldsmith Modification."

Unlike the Goldsmith modification, which simply identified certain rural census tracts located within a limited number of large urban counties (greater than 1,225 square miles), the RUCA classification system is nationwide, and classifies each census tract into one of 33 taxonomic codes (10 primary and 23 secondary). While it may make sense for purposes of ambulance reimbursement to *replace* the "Goldsmith modification" with a new definition based on the RUCA classification system, far more information will need to be provided in a Proposed Rule in order for the ambulance community to effectively comment on the change. Specifically, it is essential that the Proposed Rule define which of the 33 RUCA taxonomic codes are *proposed* to define certain census tracts as rural, and which as urban. There is currently no standard for this, and various entities use different cut-points to define rural and urban, all of which are somewhat arbitrary.

The following quote is from the website of one of the key developers of the RUCA classification system (WWAMI):

RUCA Limitations

RUCAs are one of many ways to measure the concept of rural and should not be thought of as the only way to measure it. The RUCAs are what they are and it is important that end users understand what they are and what they are not and use them only when they are appropriate.

The RUCA codes (Version 2) consist of 33 codes. These codes can be combined in many different ways depending on the purpose of the user. This is why the taxonomy was created with the 33 separate codes. While the creators of the taxonomy suggest some ways to aggregate the codes, these are just some generic suggestions and each user should review what the best aggregation is for the purpose at hand. ***Different federal and state entities (e.g., CMS, ORHP, CDC, and WA DOH) and researchers have aggregated the codes different ways to meet their needs. Usually these aggregations are into dichotomies (i.e., rural versus urban). The creators of the taxonomy do not take responsibility for the choices of others per the aggregation of the codes. In fact, sometimes we are asked for advice that is not followed.*** *On some occasions, those influenced by the third party aggregations per their eligibility for programs or per research results are critical of the RUCA taxonomy when it is how the codes were aggregated that they do not like. The RUCA codes can be custom aggregated to fill a plethora of purposes. They can also be combined with other data to refine the way they target certain types of areas (ZIP code poverty information – all 10s with 20% of their population below poverty level). They can also be used in combination with the Remote Tools provided in this web page (e.g., all 10.0 codes more than 60 minutes travel from an Urbanized Area (RUCA code 1s). For some purposes, the RUCAs may be inappropriate for a policy or research need.*

By way of specific examples, for purposes of certain rural health grants, the HRSA Office of Rural Health Policy defines eligible rural areas as those Census tracts with RUCA codes 4 through 10 *and* Census Tracts with RUCA codes 2 and 3 that are larger than 400 square miles and have population density of less than 30 people per square mile. However, the HRSA Rural Health Resource Center has published a paper titled *"An Alternative Approach to Defining Rural*

for the Purpose of Providing Emergency Medical Services (EMS)," where there is a recommendation that for EMS purposes, the definition of "rural" begin with Census tracts with a RUCA code 2, and have three other rural tiers beyond that depending upon their RUCA classification. Without more specific language in the Proposed Rule regarding what RUCA census tracts will be considered Rural or Urban, it is impossible to offer accurate comments. We would like to again recommend that the Proposed Rule be reissued with more specific information.

Further, assuming the intention is to move forward *replacing* the Goldsmith Modification with the use of some yet to be described subset of Census tracts based on their RUCA designation, will the new definition of rural Census tracts located within urban counties apply nationwide, or will it be limited only to the original Goldsmith Counties? During the Negotiated Rulemaking process there was recognition that there were indeed rural areas located within urban counties that should be eligible for the rural modifier. However, at that time the only tool that was available for the Negotiated Rulemaking Committee to consider using to identify rural areas within urban counties was the rather crude Goldsmith modification, which only looked at extraordinarily large counties located predominately in western States. Now that the nationwide RUCA system has been developed, we believe that all rural Census tracts located within urban counties should be eligible for the rural modifier.

Similar to the ZIP Code issue that was raised in the "CBSAs-Revised OMB Micropolitan Area Definitions" section above, we would like to know what specific methodology will be used to cross-walk eligible RUCA Census Tracts to ZIP Codes. ZIP Codes often cross Census Tract lines and often incorporate multiple Census Tracts. While we understand that last year the Department of Agriculture's Economic Research Service (ERS) released a ZIP Code cross-walk of RUCA's, they acknowledged it is only an "approximation." To quote from the Department of Agriculture's ERS website:

"A ZIP code approximation of the RUCA codes will be available in April of 2005. It will be based on an overlay of ZIP code areas on census tracts and not on a separate analysis of population and commuting data unique to the ZIP code geographic unit."

Thus, in a similar example to the one listed above, if a particular ZIP Code encompasses two or more Census Tracts, with 90% of it in RUCA Urban Census Tracts, and 10% in a RUCA Rural Census Tracts (yet to be defined), will that ZIP Code be assigned a "rural" or "urban" designation? In this example, if the ZIP Code were to be designated as "urban," yet the patient was picked up in the part of the ZIP Code that was in one of the RUCA rural Census Tract, would they not still be eligible for the rural payment?

Recalibration of the Ambulance Fee Schedule

We agree that it is no longer necessary to annually review the assumptions that the fee schedule were based on. However, when significant policy changes are made, as in the case of this Proposed Rule, adjustments should be made to ensure that they will not result in a net decrease in

the funding available to ambulance providers. When the current Fee Schedule was developed in the Negotiated Rule Making process, there was a requirement for budget neutrality, and as a result, in no segment of the ambulance industry was the Fee Schedule adequate to cover the full cost of providing these services.

For this reason, extra care should be taken to not reduce the current level of ambulance spending on a per transport basis in the face of rising cost factors such as fuel, insurance, medical supplies, and properly trained and experienced personnel.

Emergency Response

We do not agree with the proposed changes to this definition. There is no sense in limiting the ground ambulance emergency response modifier for emergency responses to hospitals to only provider-based ambulances. It is often the case that small rural hospitals rely on the local EMS system to provide emergency transports for critical patients from their small facilities to tertiary care centers. The changes to this definition would have a significant negative impact on the ability of non-provider based services to effectively respond to an emergency when operating in a rural area.

Inter-Hospital Specialty Care Transports

Many of the critically ill and injured patients that are transported by air in some cases require transportation by ground to airports or other locations where air transport can take place. This is especially the case in fixed wing air ambulance transports, when the patient must be moved long distances in order to receive the care they need, but must be transported to the airport in order for airplane to operate. The advanced treatments that patients receive on these transports (Critical Care Ground, or CCG) are a critical part of moving the patient, and are absolutely essential.

The change in the understanding of this terminology will have a significant impact on the way CCG transports, by definition a specialty care transport, are conducted and properly compensated for the service. Any decrease in the amount of reimbursement for already under- funded services will have a negative impact on the use of those services. If specialty care transports to and from airports, nursing homes, accident scenes, and any other area where critically ill and injured patients requiring that level of care are not properly provided, the patient will inevitably suffer the consequences of the loss of those services.

Regulatory Impact

We believe that the proposed changes in defining areas eligible for rural payments will have a significant impact on certain air ambulance providers who are operating primarily in rural areas under the current definition. AAMS strongly urges CMS to consider a multi-year phase-in period for those ambulance providers whose areas of operation are converting from rural status to urban status in order to allow providers time to prepare for the loss of the 50% rural modifier.

We also believe that the $4.6 million net loss to the ambulance industry noted in the Proposed Rule is greatly understated, although AAMS members cannot complete an analysis until the Goldsmith/RUCA change is better defined. However, regardless of the amount of the loss, AAMS believes that the net effect of this rule should be budget neutral, and that the ambulance base rates should be increased in proportion to the projected reduction in payments resulting from an increase in urban designations over rural designations. When the rural modifiers were developed during the Negotiated Rulemaking process, they were done so in a budget neutral manner. AAMS believes that if changes are made to the definitions of a rural area, these changes should also take place in a budget neutral manner, either by increasing the urban rates, or the rural modifier rates.

AAMS would also point out that, as stated in the overview above, that by adding back this amount to the ambulance "pool" of dollars, it must be recognized that air ambulance providers that operate in affected areas will be much more significantly impacted than ground ambulance providers given the larger current rural modifier (50% vs less than 20%). Therefore, air ambulance rates should be increased at a higher percentage than ground ambulance rates.

AAMS would like to thank CMS again for the opportunity to comment on this proposed rule, and we welcome any further opportunity to discuss these comments with representatives of CMS. If there are any further questions or any need for clarification of our concerns or comments, please contact the AAMS National Office at the numbers listed above.

Sincerely,

Edward R. Eroe, CAE, CHE, CMTE
President, AAMS
Partner/CEO,
MedServ Air Medical Transport
Platte City, Missouri

Dawn M. Mancuso, MAM, CAE
Executive Director/CEO

17

JUL 25 2006

LaGrange Township

Established 1829

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Township Trustee
Robert K. Wright
61092 Spencer Rd.
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July 19, 2006

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1317-P
P.O. Box 8017
Baltimore, Maryland 21244-8017

RE: CMS-1317-P; Medicare Program; Revisions to the Payment Policies of Ambulance Services under the Fee Schedule for Ambulance Services.

We are commenting on the proposed rule change that would change the classification method for determining rural areas and payment to ambulance services. Under the proposed rule, our ambulance service area would be changed from rural to urban. Our Township population is currently just over 2,000 residents. The largest town in our county has a population of 5,968. Such a classification is not logical and will be burdensome on our taxpayers as we already need to subsidize our ambulance service so that we can have an ambulance near our community. This money will have to be made up some where, either by raising more taxes to fund the subsidies already paid to the ambulance service, or charging our older citizens who are on Medicare for this lost financial aid.

We urge your reconsideration of this proposed rule and that CMS would further their efforts to recognize the cost of providing ambulance service to rural communities like ours.

Sincerely,

The LaGrange Township Board
Naida Covyeou-Wallace, Supervisor
Naomi Criswell, Treasurer
Amy Juroff, Clerk
Paul File, Trustee
Rob Wright, Trustee

18.

Med Flight of Ohio

JUL 25 2006

camts
Commission on Accreditation of Medical Transport Systems

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July 21, 2006

Mark B. McClellan, MD, Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1317-P; Medicare Program; Revisions to the Payment Policies of Ambulance Services under the Fee Schedule for Ambulance Services

Dear Dr. McClellan:

Ohio Medical Transportation (dba: MedFlight of Ohio) submits the following comments on the Centers for Medicare and Medicaid Services (CMS) Proposed Rule entitled "*Medicare Program; Revisions to the Payment Policies of Ambulance Services under the Fee Schedule for Ambulance Services*" ("Proposed Rule") 71 Fed. Reg. 30358 (May 26, 2006). **MedFlight** provides critical ambulance services to the Medicare beneficiaries and residents within the state of Ohio and surrounding areas.

Summary of Comments

Our organization strongly objects to the **proposed changes** to the definitions of "emergency response" and "specialty care transport (SCT)" that were adopted by the Negotiated Rulemaking Committee (NRM Committee) for the Medicare Ambulance Fee Schedule and subsequently incorporated into the Final Rule of January 22, 2002. To our knowledge, CMS has not articulated any public policy interest or legal rationale that would require these changes. MedFlight feels that the noted changes would definitely prove to be detrimental to Medicare beneficiaries.

Regarding the revised geographic determinations for rural and urban, we commend CMS on adopting Rural Urban Commuting Areas (RUCAs) as part of the most recent Goldsmith modification for identifying rural areas within urban tracts. As a member of the American Ambulance Association, we have been supportive of using RUCAs as the sole geographical determination for ambulance services. While using the updated Goldsmith modification and thus RUCAs as only a modifier falls short of this objective, it is at least a step in the right direction.

Prior to implementing the new OMB standards for Core-Based Statistical Areas (CBSAs) as the primary determination, we recommend that CMS take several steps which include



JUL 24 2006

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July 21, 2006

Mark B. McClellan, M.D., Ph.D., Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1317-P
Mail Stop C-26-05
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Baltimore, MD 21244-1850

Re: CMS-1317-P; Medicare Program; Revisions to the Payment Policies of Ambulance Services Under the Fee Schedule for Ambulance Services

Dear Dr. McClellan:

American Medical Response ("AMR") appreciates the opportunity to comment on the above-referenced Proposed Rule, entitled "Medicare Program; Revisions to the Payment Policies of Ambulance Services Under the Fee Schedule for Ambulance Services" (the "Proposed Rule"). AMR is the nation's leading provider of emergency and non-emergency ambulance services. We operate in over 250 communities nationwide, transporting approximately 4 million persons annually. We employ 17,000 medical and administrative personnel.

We will summarize our comments before discussing them in detail. We will also address our areas of concern in the order they appear in the Proposed Rule.

SUMMARY OF COMMENTS

Rural Classification Issues. AMR concurs in the adoption of Rural Urban Commuting Areas ("RUCAs") as part of the most recent Goldsmith modification for identifying rural areas within urban tracts. While we would prefer the use of RUCAs as the sole basis for determining rural and urban areas, the use of RUCAs as a modifier in the updated Goldsmith modification constitutes an improvement. We also agree that the Office of Management and Budget Core-Based Statistical Areas ("CBSAs") standard should identify Micropolitan Statistical Areas as being non-urban. We believe, however, that the resultant reclassification may be premature. As you are aware, the Government Accountability Office ("GAO") is currently conducting a study regarding ambulance rural classification issues. We recommend that CMS wait until the GAO study is complete before undertaking changes affecting this classification.

If CMS nevertheless proceeds with these changes, we are concerned about the financial impact of this reclassification on suppliers and providers ("suppliers") who will be adversely affected by it. We will suggest below some steps to mitigate the financial impact on those suppliers, which would also provide CMS an opportunity to review the findings of the pending GAO report before finalizing the rural classification definition.

Definitions of "Specialty Care Transport" and "Emergency Response". AMR agrees with CMS regarding the need for clarification of the definitions of "emergency response" and "specialty care transport" ("SCT") found in the current Ambulance Fee Schedule Rule (the "Fee Schedule Rule"). We disagree, however, with the specific changes CMS proposes to make to those definitions because they are inconsistent with the definitions agreed upon by the Negotiated Rulemaking Committee (the "Committee") which provided the framework for the Fee Schedule Rule. The Committee included representatives of the Health Care Financing Administration ("HCFA"), now CMS, as well as other stakeholders. Part of the charter of the Committee, as dictated by section 4531(b)(2) of the Balanced Budget Act of 1997 ("BBA"), was to develop "definitions for ambulance services that link payments to the types of services furnished." The Committee reached consensus on a number of issues, including the definitions of "emergency response" and "SCT". A copy of the Committee Statement, signed on February 14, 2002, setting forth the agreed-upon definitions, is enclosed. The Department of Health and Human Services, through HCFA, agreed to use the Committee's statement to the maximum extent possible, consistent with its legal obligations, as the basis for the Fee Schedule Rule.

More importantly, the proposed changes to the definitions of "emergency response" and "SCT" would be counter-productive and harmful to beneficiaries. The proposed clarification of SCT would eliminate reimbursement for SCT services required by patients who truly need them, potentially making these services unavailable to them. The proposed clarification of what constitutes an "emergency response" actually confuses, rather than clarifies, the meaning of that phrase. In lieu of these changes, we will suggest clarifications to both definitions that are consistent with the Committee's intent as well as with CMS's own pronouncements.

We will elaborate on these concerns in our detailed comments below.

DETAILED COMMENTS

1. CBSAs-Revised OMB Metropolitan Area Definitions and RUCAs

We are pleased that CMS is proposing to adopt Rural Urban Commuting Areas ("RUCAs") as part of the most recent Goldsmith modification for identifying rural areas within an urban track. We also concur in the change that would identify Micropolitan Statistical Areas as being non-urban. However, these changes may be premature. In response to concerns on the part of the Committee that the system it had developed for recognizing the additional cost if providing ambulance services in low volume rural areas is imperfect, CMS agreed to review the cost and demographic problems presented by this issue to improve the degree to which the ambulance payments system would recognize these additional costs. The GAO has been asked by Congress to evaluate this issue, and its report is expected to be issued in the near future. Implementing CMS's proposed changes at this point in time may preempt that

report, which will likely provide a more complete and accurate basis for changes in the current rural payment system and definition. We therefore recommend that CMS postpone any changes in the current definition until the report has been issued.

We believe that such forbearance would also be consistent with Congressional Intent, as indicated by certain provisions in the Medicare Modernization Act, P.L.108-173 ("MMA"). As you are aware, several provisions of that Act were designed to provide temporary relief to rural providers until the current study has been completed and a more reasonable system is enacted. For example, the MMA included adjustments for certain long trips, assistance for providers in low population density areas, and a 2% increase in payment rates for rural areas. These changes were made against the backdrop of the current system, and some of them will remain in place until 2010.

If CMS nevertheless chooses to implement these changes prior to completion of the GAO report, we are concerned about the impact these changes will have on current rural suppliers. As CMS has acknowledged, these changes will result in a shift in many areas from rural to urban. For obvious reasons, suppliers operating in these areas may have difficulty adjusting to a potentially dramatic loss in revenue. To mitigate that impact, ambulance trips in rural areas that obtained some form of relief that was enacted in the MMA should continue to be treated in accordance with the terms of those provisions for the period specified by Congress, regardless of their new classification. In addition, ambulance suppliers adversely affected by the proposed changes should be provided with the same protections that CMS provided to hospitals adversely affected by the CBSA and RUCA changes in the Inpatient Hospital Final Rule for 2005. See 69 Fed. Reg. 48916, 49032 (August 11, 2004). Specifically, any area that would lose its rural designation because of these changes should be protected by a three year "hold harmless" to allow providers to adjust their budgets and business practices in response to the rate changes.

Finally, we suggest that CMS put into place a formal reclassification process through which suppliers could present unique circumstances that may justify a continued rural classification for specific areas.

2. <u>Specialty Care Transport</u>

CMS proposes to restrict the delivery of SCT services to patients being transported between hospitals. Although the preamble to the Proposed Rule characterizes this revision as a "clarification," in reality it constitutes a major change that flies in the face of the definition agreed upon by the Committee and incorporated into the Fee Schedule Rule.

Currently, SCT is defined as "*interfacility* transportation of a critically injured or ill beneficiary. . . at a level of service beyond the EMT-paramedic," based on the scope and practice of an EMT-paramedic under state and local laws. The current definition of SCT, including the reference to "interfacility transports," was carefully negotiated and agreed-upon by the Committee and its Medical Issues Workgroup (the "Workgroup"). Initially, the strong sentiment among some Workgroup members was that the definition should include patients transported from accident scenes. Ultimately, the Workgroup and the Committee compromised on this issue and settled on a definition that characterized SCT as "a level of inter-

facility transport service. . . " Through its participation in both the Workgroup and the larger Committee, CMS was aware of, and agreed to, this compromise when it executed the Committee Statement.

We are aware that CMS used the word, "interhospital" in explaining the SCT definition in the preamble to the proposed Fee Schedule Rule published on September 12, 2000. However, the proposed regulatory text itself correctly used the word, "interfacility." More importantly, after this discrepancy was pointed out through comments to the rule, CMS retained the word "interfacility" in the final definition included in the final Fee Schedule Rule.

Moreover, since publication of the Fee Schedule Rule, CMS has indicated on a number of occasions, in the Ambulance Open Door Forum calls and other informal communications, that "interfacility" encompasses transports to or from nursing homes. In 2005, the CMS Region V office instructed a contractor, Wisconsin Physicians Service Insurance Corporation, to pay claims at the SCT level for transports between SNFs and hospitals when other criteria were met.[1] In light of the foregoing, it is apparent that CMS has changed its view regarding the scope of the SCT definition.

We urge the agency to consider the implications of this proposed change. As you are aware, the acuity level of patients receiving care in a SNF after transitioning from a hospital has been steadily increasing, as SNF care has become more sophisticated and CMS has sought to reduce hospital lengths of stay. As a result, patients being transported between hospitals and nursing homes are more likely than ever to require advanced levels of care that can only be provided by specialty personnel with skills and training above the standard paramedic level. A substantial number of these patients are on ventilators or other life sustaining equipment that requires monitoring by specialty medical personnel. Indeed, in many jurisdictions patients on ventilators or certain other types of equipment are required by state or local laws or protocols to be accompanied by a specially trained paramedic, nurse or other specialty personnel, regardless of whether the origin or destination is a SNF versus a hospital. If CMS eliminates reimbursement for these transports, beneficiaries and their caregivers will face an untenable choice: Ambulance suppliers will either be compelled to provide such services without adequate reimbursement or, if suppliers are either unwilling or unable to do so, these patients will be transported using a level of care that may be insufficient to meet their needs. Neither outcome is acceptable.

While we disagree with the proposed change in the SCT definition, we agree that a clarification of the definition, consistent with the Committee's definition, is required. Currently, there are two issues on which the carriers display a wide variation of practice, often resulting in inappropriate denials.

First, some carriers are interpreting the reference to "critically injured or ill beneficiary" in the existing definition in an overly restrictive fashion that denies SCT coverage for some patients who clearly need that level of care. The Committee intended for

[1] See Medicare Part B Communiqué, Wisconsin Physicians Service Insurance Corporation, June 2005, page 8.

the SCT level of care to be reimbursed in any circumstance where appropriate state or local medical protocols or prevailing standards of care require the use of specialty personnel during transport. We believe the reference to "critically injured or ill beneficiary" should be read as synonymous with a patient whose medical condition requires care above the regular scope of a paramedic, rather than as a separate and additional requirement. Put another way, patients who need this level of care, based on local protocols or prevailing standards of care, should be presumed to be critically injured or ill. We do not believe the Committee ever intended to impose an *additional* requirement such that only a subset of patients in need of the SCT level of care would be entitled to receive it. An interpretation that creates a second and separate requirement would necessarily result in denial of SCT coverage for some beneficiaries who clearly need that level of care.

Second, some carriers are interpreting the SCT definition as providing for reimbursement only when an actual intervention (e.g., activation of a ventilator or a change in its setting) by specialty personnel is required. This overly narrow interpretation flies in the face of state or local medical protocols or prevailing standards of care requiring that the patient be accompanied by specialty personnel to monitor the patient, *in case* an intervention is required during transport. Again, the result of this narrow interpretation is that patients who require SCT may not be able to receive it, or ambulance suppliers who provide it may not be reimbursed for doing so.

To address both these issues, we urge CMS to clarify the definition of SCT so that it is consistent with state or local protocols and prevailing standards of care. Reliance on such protocols and standards was a central premise of the Committee's agreed-upon report. We therefore believe that reliance on such considerations in defining "specialty care transport" would be consistent with the intent of the Committee. To effectuate the clarifications we are proposing, we suggest that the definition of "specialty care transport" be revised to state as follows:

> *Specialty care transport (SCT)* means interfacility transportation of a critically injured or ill beneficiary by a ground ambulance vehicle, including medically necessary supplies and services, at a level of service beyond the scope of the EMT–Paramedic. SCT is necessary, and a beneficiary is deemed to be critically injured or ill, when the beneficiary's condition, according to applicable local and/or state standards of practice, requires ongoing care, including monitoring of specialty equipment needed by the beneficiary, that must be furnished by one or more health professionals in an appropriate specialty area, for example, nursing, emergency medicine, respiratory care, cardiovascular care, or a paramedic with additional training.

3. **Emergency Response**

CMS proposes to change the definition of "emergency response" to read as follows:

> Emergency response means that an ambulance entity (1) maintains readiness to respond to urgent calls at the BLS or ALS-1 level of service and (2) responds immediately at the BLS or ALS-1 level of service to 911 calls, the equivalent in areas without a 911 call system *or radio calls within a hospital system when the ambulance entity is owned and operated by the hospital.* (Emphasis added.)

In addition to adding the emphasized language, this revised definition would eliminate part of the current definition which states, "an emergency response is one in which the ambulance entity begins as quickly as possible to take the steps necessary to respond to the call." (42 C.F.R. §414.605.)

According to the preamble to the Proposed Rule, the intent behind this change is to limit the situations in which hospital to hospital transports can be billed as an emergency response. We respectfully submit, however, that the proposed change fails to provide any meaningful clarification on this issue, but instead creates an arbitrary distinction between ambulances which are "owned and operated by the hospital" and dispatched by "radio calls" on the one hand, and other ambulances on the other. CMS fails to explain how the ownership of the ambulance or "ambulance entity" or the communication medium by which the call comes in has any bearing on whether the patient requires an emergency response.

As CMS acknowledged in the preamble to the proposed and final Fee Schedule Rules, a higher level of payment for an emergency response is intended to compensate ambulance suppliers for the additional costs incurred in maintaining the readiness to undertake an immediate response. CMS has also acknowledged in program memoranda[2] and in other communications such as Open Door Forum calls that it is the condition of the patient as reported at the time of response that determines whether an emergency response is warranted. Neither the Fee Schedule Rule nor any subsequent clarification has suggested that either the ownership or location of the ambulance is relevant to whether an emergency response is justified. Regardless of ownership, ambulances may be posted to a hospital location for a number of reasons, including the location of crew quarters at the facility. If an ambulance stationed at or near a hospital maintains a readiness to respond immediately, and a patient requires such a response, there is no reason whatsoever that coverage for that level of service should be denied simply because the patient originated at the facility, or because the ambulance is not owned by the hospital. Similarly, as discussed below, the medium by which the call comes in is irrelevant.

Examples of situations in which an emergency response to a hospital would clearly be warranted, regardless of ambulance ownership, location or mode by which the call came in, include (a) a patient with an emergent condition who is delivered to a hospital that lacks the capacity to adequately treat him or her and must be emergently transported to another facility, or (b) a patient previously admitted to a hospital who develops a new emergent condition that cannot be treated there and must be emergently transported to another facility. In both of these situations, if the transferring physician determines that an

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[2] See, e.g., Transmittal AB-03-106 (July 25, 2003), page 6: "An emergency is determined based on the information available to the dispatcher at the time of the call, based on standard dispatch protocol."

immediate transfer is necessary, and the ambulance supplier has incurred the cost of readiness in anticipation of such situations, the requirements for an emergency response should be deemed met regardless of the ownership status, the location of the ambulance or the means by which the call came in.

Although we disagree with CMS's proposed changes in the definition of "emergency response," we agree that clarification of the current regulatory definition is warranted to incorporate guidance CMS has provided since the Fee Schedule Rule was issued. As indicated above, the current definition refers only to an immediate response "to a 911 call or the equivalent in areas without a 911 call system." In a number of program memoranda and other pronouncements, CMS has clarified that "emergency responses" also include calls received by radio or over seven-digit lines, even in areas which have a 911 system, if an immediate response is warranted based on the information available to the dispatcher at the time of the call. For example, in one key CMS Transmittal, Number AB-02-130 (September 27, 2002), entitled "Definition of Ambulance Services," CMS provided the following clarification:

> **Definition:** Emergency response is a BLS or ALS-1 Level of service [that] has been provided in immediate response to a 911 call or equivalent. An immediate response is one in which the ambulance provider/supplier begins as quickly as possible to take the steps necessary to respond to the call.
>
> **Application**: The phrase "911 or equivalent" is intended to established the standard that the nature of the call at the time of dispatch is the determining factor. *Regardless of the medium by which the call is made* (e.g., a radio call could be appropriate) the call is of an emergent nature when, based on the information available to the dispatcher at the time of the call, it is reasonable for the dispatcher to issue an emergency dispatch in light of accepted, standard dispatch protocol. *An emergency call need not come through 911 even in areas where a 911 call system exists.* (emphasis added.)

Similar clarification is provided in the Medicare Claims Processing Manual (CMS Pub. 100-04), Section 10.3, under the definition of "advanced life support assessment," where CMS recognizes that a call warranting an "emergency response" may either come in from a local 911 number or "directly to the ambulance provider/supplier."

Because the Fee Schedule Rule is currently unclear on this issue, we recommend that CMS change the current definition of "emergency response" to clarify this point. Specifically, we propose that the definition be revised, consistent with the foregoing CMS pronouncements, to state as follows:

> Emergency response means responding immediately at the BLS or ALS-1 level of service to a 911 call or the equivalent ~~in areas without a 911 call system~~. An immediate response is one in which the ambulance supplier begins as quickly as possible to take the

steps necessary to respond to the call. Regardless of the medium by which the call is made, the call is of an emergent nature when, based on the information available to the dispatcher at the time of the call, it is reasonable for the dispatcher to issue an emergency dispatch in light of accepted, standard dispatch protocol. An emergency call need not come through 911 even in areas where a 911 call system exists.

The language added here comes directly, almost verbatim, out of CMS's clarification in Transmittal number AB-02-130, which has been repeated or alluded to in subsequent transmittals and communications. The foregoing proposed revision would explicitly incorporate two important elements of the "emergency response" definition as currently being implemented by CMS and the carriers: (1) An "emergency response" can be based on a call to the supplier's seven-digit number, even in areas which have a 911 system; and (2) it is the nature of the patient's condition as reported to the dispatcher at the time of response that is dispositive. Neither of these key elements is currently found in the existing definition.

CONCLUSION

In summary, AMR recommends that the Proposed Rule be revised as follows:

a. Changes to the rural definition should be postponed until after the GAO has issued its report and Congress has had an opportunity to act on it. To the extent any changes are made prior to that time, suppliers who have received congressionally-mandated increases in reimbursement under the MMA should continue to receive those benefits for the time period specified by Congress. Additionally, suppliers adversely affected by a reclassification of their transports should be protected by a three-year "hold harmless." CMS should also establish a mechanism for exempting certain areas from reclassification based on unique circumstances.

b. The definition of "specialty care transport" should continue to reference "interfacility" transport, and should be interpreted to include otherwise qualifying transports in which the origin and/or the destination is a SNF, as intended by the Committee. In addition, the reference to "critically injured or ill" beneficiaries should be modified so that it is clear to suppliers and carriers that all patients whose medical condition requires a transport by personnel with skills above the paramedic level, based on state or local medical protocols or standards or care, are appropriate for SCT services. Finally, the SCT definition should be revised, consistent with state or local medical protocols and prevailing standards of care, to make it clear that SCT reimbursement is appropriate in cases where personnel above the standard paramedic level are required to monitor a patient, even if no actual intervention is required.

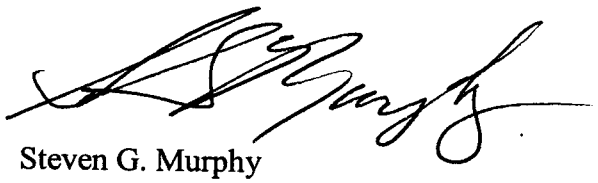
c. The proposed change in the definition of "emergency response," referencing "radio calls to the hospital system when the ambulance entity is owned and operated by the hospital," should not be made. However, the definition should be clarified in two important respects to codify in regulation interpretations that CMS has provided through program transmittals and in the Medicare Benefit Policy Manual. First, the definition should be revised to clarify that seven-digit calls may justify an emergency response even in areas that have a 911 system. Second, the definition should explicitly state that it is the condition of the

patient as reported to the dispatcher that determines whether an emergency response is warranted.

Thank you for considering our comments. If you have any questions or would like us to elaborate on any of these comments, please do not hesitate to contact me.

Very truly yours,

AMERICAN MEDICAL RESPONSE



Steven G. Murphy
Executive Vice President
Government and National Services

Healthcare Innovations, Inc.
P.O. Box 1348
Benson, AZ 85602

July 18, 2006

Centers for Medicare & Medicaid Services
Dept. of Health and Human Services
Attention: CMS-1317
P O Box 8017
Baltimore, MD 21244-8017

File Code CMS-1317-P

Dear Sir,

We appreciate the opportunity to comment on the rule changes contained in CMS-1317-P as the changes directly impact our operations.

Healthcare Innovations, Inc. operates the only ambulance service in Southeastern Arizona in sparsely populated northern Cochise County. Hundreds of square miles with three incorporated towns and a total population of about 20,000. Tourism, farming and ranching are the main source of income. The population increases in the winter months about 10% with snowbirds enjoying the RV lifestyle. The Demographics include many retirees and working class with low wage service industry making up the majority of the jobs. We operate three ambulance stations stretched across the county along Interstate 10 about 35-40 miles apart. There are two small community hospitals in our service areas. This one service area is made up of the same geographic area where four ambulance services once operated. The other ambulance services no longer exist because the income available from the payor mix in the area could not cover the cost of operations.

The population is about 70% Medicare and Medicaid patients and fourteen percent is patients, which includes illegals that never pay a cent for their services. The amount we receive in reimbursement from Medicare and Medicaid are <u>less</u> than the amount it costs to provide the services. This leaves sixteen percent of those we serve subsidizing the other 84% of the users of our services. Our rates, approved by the Arizona Department of Health Services are almost three times as high as the Medicare allowable which reflects the extreme subsidy the private insurance and private paying users are paying to subsidize Medicare and Medicaid patients.

We raise this issue only because two of the proposed rule changes in CMS-1317-P would reduce the amount we currently receive from Medicare.

The following are our comments on those rules that we feel would effect our operations in a negative way.

CBSAs- Revised OMB Metropolitan Area Definitions

We have not seen the zip code list of those areas affected, but we believe we are so rural that it is inconceivable that a change would affect us.

CALVIN TOWNSHIP

W. J. Robinson Community Building
P.O. Box 305
18727 Mt. Zion St.
Cassopolis, MI 49031

July 17, 2006

Centers for Medicare and Medicaid Services
Department of Health and Human Services

Attention: CMS-1317-P

Re: CMS-1317-P Medicare Program; Revision to the Payment Policies of Ambulance Services under the Fee Schedule for Ambulance Services.

RESOLUTION

In a Regular Meeting of the Calvin Township Board, Cass County MI, July 11, 2006, **Board Member Eddie Ballard motioned supported by Keith Carter** to reject the CMS-1317-P proposal to decrease ambulance funding for Medicare and Medicaid patients, also changing Cass County designation area to rural.

All Township Board Members were present (5).

Ayes voted-5
Nays voted-0, motion carried.

If this plan is put into effect by CMS, it will prove to be a tremendous hardship on our Senior Citizens as well as some of our less fortune residents who are of very low income and or are recipients of Medicaid; in addition to this it would put a financial burden on the Cass County Area Life Care Ambulance Service.

Therefore: The Calvin Township Board disagree with this plan proposal of CMS-1317-P and will not support its effort to put it into action as afore stated in this Resolution.

This Resolution is respectfully submitted.

Sincerely,

Leozie S. Broadnax
Calvin Township Clerk

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JUL 26 2006

Richard H. Anderson Chief Executive Officer
12125 Technology Drive Eden Prairie, MN 55344
Tel 952 833 6207 Fax 952 833 7079

July 12, 2006

Mark B. McClellan, Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Room 445-G
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Administrator McClellan:

Ingenix submitted extensive comments in response to the Centers for Medicare and Medicaid Services proposed rule related to the fiscal year 2007 inpatient hospital prospective payment system. As a follow up to that correspondence, we want to make sure you are directly aware of our offer to provide the All-Payer Severity-adjusted DRG reimbursement methodology ("APS-DRGs"), which was developed by Ingenix, free of charge to CMS and to provide it to the industry in an open and transparent fashion as a utility.

The independent and highly respected Lewin Group has conducted a study comparing the APS-DRG system as an alternative methodology to the newly proposed consolidated severity-adjusted system (CSA-DRGs). The Lewin evaluation concludes that Ingenix's modified APS-DRGs are simpler and more flexible than CSA-DRGs. As a result, the APS-DRGs are likely to be more transparent, easier for hospitals to implement, and easier to maintain and improve over time than CSA-DRGs. The Lewin Group further found that APS-DRGs explain at least as much variance in patient severity as CSA-DRGs and are less likely to underpay high-casemix hospitals than CSA-DRGs. Attached is a copy of the full Lewin study.

We look forward to meeting with you in person to discuss our concerns related to the proposed rule as well as to discuss the APS-DRG methodology which we believe deserves serious consideration by CMS and the general public as an alternative to the proposed CSA-DRGs.

Thank you for your time and attention.

Sincerely,

R H Anderson

Richard Anderson

The LEWIN GROUP

An Evaluation of APS-DRGs In Comparison to the Newly Proposed CSA-DRGs

Final Report

Prepared for:

Ingenix

Prepared by:

Allen Dobson, Ph.D.
Joan E. DaVanzo, Ph.D., M.S.W.
Julia Doherty, M.H.S.A.
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W. Pete Welch, Ph.D.
Robert Book, Ph.D.

June 12, 2006

TABLE OF CONTENTS

EXECUTIVE SUMMARY

The fairness and efficiency of Medicare's system of paying acute care hospitals depends, in part, on the system's ability to distinguish cases according to the patient's severity of illness. To better meet this objective, the Centers for Medicare and Medicaid Services (CMS) proposed using consolidated severity-adjusted DRGs (CSA-DRGs) in its Notice of Proposed Rulemaking (NPRM) dated April 25, 2006. Ingenix has developed the Medicare modified all patient-severity DRGs (or "modified APS-DRGs")[1] and proposes that CMS formally consider APS-DRGs as an alternative to the CSA-DRGs. The Lewin Group was engaged by Ingenix to conduct an independent evaluation of its APS-DRG system in comparison to CSA-DRGs.

As part of this evaluation, we reviewed the documentation for the two systems, examined the NPRM and descriptions of earlier systems, and performed a series of comparative regression analyses. Our evaluation was constrained by the extent of the information available on APR-DRG grouping logic and by the inherent time constraints associated with responding to proposed rulemaking.

Primary Assessment

After evaluation, The Lewin Group concluded that Ingenix's modified APS-DRGs are fundamentally simpler and more flexible than CSA-DRGs. Because of this simplicity and flexibility, the modified APS-DRGs may be more transparent, easier for hospitals to implement, and easier to maintain and improve over time than CSA-DRGs. Furthermore, the Lewin Group found that APS-DRGs explain at least as much variance in patient case costs as CSA-DRGs and are less likely to underpay high-casemix hospitals than CSA-DRGs.

APS-DRGs are a hybrid of two analytic systems already in use by CMS:

- Each case is assigned to one and only one cell (i.e. DRG) [2]; and
- Within a cell, a case may involve an add-on payment that reflects the case's greater than average severity. This add-on payment amount is calculated via regression analysis as with CMS' current risk adjustment systems.

APS-DRGs build on CMS' current co-morbidity conditions and complications (CC) listings and exclusion logic but recognize the differences in severity among patients. On the one hand, this represents a paradigm shift in patient categorization methodology for acute care hospital payments - one that better reflects varying levels of severity for inpatients within DRG based cells. On the other hand, CMS currently uses similar systems to pay psychiatric hospitals and managed care organizations.

The goal of CMS in selecting a severity adjusted DRG system is to limit the within-group variation in resource use to improve homogeneity within DRGs, and, at the same time, adequately reflect an individual patient's severity, as CMS has been tasked to do by the

[1] The original APS-DRGs were developed by HHS, Inc. , which was acquired by Ingenix in May 2005. The APS-DRG system has been modified for the Medicare population.
[2] The current DRG system does have an add-on payment for technology but no add-on payment for severity.

Medicare Payment Advisory Commission (MedPAC). The final classification system selected also needs to meet CMS' longstanding goals of administrative feasibility and transparency so that hospitals can fully understand its expectations and rules.

CMS documents and other key literature discuss the following key criteria for evaluating severity-based DRG systems and the extent to which they offer the following features or enhancements to the DRG system without undue implementation burdens (see references).

- Maintaining transparency, administrative ease and public availability;
- Limiting costs of implementation and maintenance;
- Limiting manipulation potential;
- Including clinically meaningful severity assessments; and
- Enhancing ability to systematically predict resource use.

Transparency, Administrative Ease and Public Availability

Transparency is an issue that occurs across many aspects of government and some aspects of business. In a democracy, transparency (i.e., publicly available information) is considered desirable except in special exceptions. For instance, under the Freedom of Information Act (FOIA), citizens can obtain information on a wide range of topics, but not all (e.g., personnel matters). CMS payment policies have generally been transparent.

In the case of DRGs, transparency results in an understanding of the logic of DRG systems, which is important for two reasons:

1. For policy creation, understanding facilitates public discussion; and,
2. For program implementation, understanding facilitates both the initial implementation and long-term maintenance.

Unlike the proposed CSA-DRGs, each component of the modified APS-DRG system can be readily examined. The first part of the hybrid system incorporates the existing CC listings and exclusion logic, which are already publicly available. The second part involves an add-on payment for each additional comorbidity. Understanding the general approach does not require a detailed knowledge of medical conditions and coding. While there undoubtedly are subtleties, analysts will be able to quickly understand the basic logic of this approach.

To date, CMS has not provided adequate documentation (e.g., CC lists and the exclusion logic tables) to allow users to fully understand the CSA-DRG assignment process. This may be, in part, due to the iterative approach taken in refining the system. Because some cases are assigned to a given CSA-DRG, apparently based on different combinations of secondary diagnoses and potential exclusions, one cannot reconstruct (i.e., reverse engineer) the assignment algorithm from the DRG assignment of specific cases. It is our conclusion that the CSA-DRGs are more difficult for potential users to understand than the modified APS-DRGs. Transparency is a critical concern as DRG assignment has become more sophisticated and complex.

A higher degree of transparency will also mean that all the technical aspects of a system (for example, the DRG grouper, assignment of severity, etc.) will be available to the public. This is particularly critical in ensuring CMS can continue to engage in an on-going public dialogue regarding changes in hospital admitting practices, payments, and technology and actively seeks the participation and feedback from hospitals. Being able to readily understand program rules allows coders to more appropriately and efficiently reflect resource utilization in their every day coding and management practices.

Limiting Costs of Implementation and Maintenance

Regardless of the severity system ultimately selected, CMS will incur costs in refining the approach before the issuance of a final rule, throughout implementation, and beyond. The less significant the changes are in terms of the overall structure of the classification system, the fewer costs that will be incurred for both the government and provider community. The CSA-DRG system and its complex algorithms, although based on APR-DRGs which have been carefully conceived over many years of research and development, make it less transparent, flexible or amenable to later refinement and modifications. By forgoing transparency when introducing such new systems, CMS may ultimately increase its implementation and maintenance costs beyond what might be required to implement the modified APS-DRGs.

Manipulation Potential

Another key concern of policymakers, since the inception of the IPPS, has been to limit manipulation potential which any system is vulnerable during implementation. As the DRG system becomes more complex, changes proposed to add a severity of illness adjustment to the system should account for the potential for inappropriate manipulation in reporting, coding, and grouping procedures, as well as assigning diagnoses to improve reimbursement beyond that intended by the system.

Part of the reason CMS has been reluctant to implement a severity refined DRG system is a fear of upcoding and manipulation, as occurred at the inception of the IPPS in 1983. The more transparent the system, the easier the system will be to manipulate, since the results that coding will produce will be clear. However, there is upcoding potential in both proposed systems, and this may be the price to be paid in order to achieve the benefits of more powerful severity measurements. In any event, CMS, as it has in the past, always has the option to disentangle real casemix increases from "DRG creep" by reducing the rate of increase accordingly in the subsequent year. And finally, CMS has exactly the same problem with its capitated risk adjustment system so its adaptive policies will be well formulated.

Clinically Meaningful

Any proposed new approach to recognize severity of illness must also be appropriate and consistent in terms of its clinical approach. The APS-DRG system has structured the clinical knowledge base into its system in a tabular form; conversely, the CSA-DRG system requires multiple decision rules imbedded in computer codes. The modified APS-DRGs use the same basic approach in terms of the first phases of the assignment process where clinical issues are explicitly considered.

Systematically Predicting Treatment Cost

The two casemix systems use approximately the same number of DRGs. However, only the APS-DRG system includes an add-on to the weights (and hence payments) that recognizes the number of independent comorbidities. Because of this second component, we hypothesized that APS-DRGs predict treatment cost (or resource utilization) better than CSA-DRGs. We test this hypothesis as part of our analyses.

The more accurately a casemix system predicts resource use, the better suited it is to support payment. In this context statistical performance has two components: the ability to explain variance (as measured by R-squared) and plausible coefficients. Regarding the latter issue, a ten percent increase, for instance, in casemix across hospitals should be associated with a ten percent increase in cost; that is, cost should have an elasticity of 1.0 with respect to casemix.

To assess these casemix systems, we performed regression analyses using 2004 Medicare MedPAR data. Cost, standardized for payment variables, was regressed on the various casemix measures. [3] From the results, we drew two conclusions. First, modified APS-DRGs explain at least as much variance as CSA-DRGs. Second, costs have elasticity above 1.0 with respect to CSA-DRGs but only slightly above 1.0 for APS-DRGs, so both systems would underpay high-casemix hospitals. However, the problem is substantially less under APS-DRGs.

Conclusion

After a careful assessment, The Lewin Group has concluded that the modified APS-DRGs are worthy of consideration by CMS and the public policy community as an alternative to the proposed CSA-DRGs. The modified APS-DRGs offer a simpler, more transparent, and perhaps more accurate approach by essentially extending CMS' current approach to DRGs and adding the value of risk adjustment type methodologies. CMS already uses this hybrid methodology to pay psychiatric hospitals and managed care organizations. We found that APS-DRGs are statistically sound.

CMS has traditionally made its payment policies transparent. Regardless of what system CMS implements, we urge it continue this tradition by making the grouper logic entirely transparent and publicly available at minimal cost.

[3] In one of its publicly available datasets, CMS has applied the CSA-DRG software to all the discharges in 2004. We had access to this dataset, not to the algorithm.

I. Background and Purpose

On April 25, 2006, the Centers for Medicare & Medicaid Services (CMS) issued proposed changes to the Medicare hospital inpatient prospective payment system (IPPS) based on the recommendations provided by the Medicare Payment Advisory Committee (MedPAC). These recommendations included the addition of severity of illness refinements to current diagnosis related groups (DRGs) and the application of hospital-specific relative value (HSRV) weights to DRGs in order to increase the accuracy of Medicare payments and prevent hospitals from "cherry picking" cases that would be the most profitable.

The proposed consolidated severity-adjusted DRGs (CSA-DRGs) are a version of 3M's current all patient-refined DRGs (APR-DRGs), currently used by the State of Maryland for hospital payment and by a number of other state health information agencies and other organizations for quality monitoring. In the proposed rule, CMS has requested "public comments on whether there are alternative DRG systems that could result in better recognition of severity than the consolidated severity-adjusted DRGs" they are proposing.

The Lewin Group was engaged by Ingenix to conduct an independent evaluation of its proposed alternative to the CSA-DRGs – the modified APS-DRGs. In this paper, we discuss the findings of our evaluation and the methods through which we compared the modified APS-DRGs to the CSA-DRGs. We present evaluation criteria, describe the origins and approach of each system, and describe how the systems compare to each other. We then provide a qualitative and quantitative assessment of the modified APS-DRGs and the unique system they have developed to assign individual patient weights which takes into account both casemix and adds risk adjustments for additional independent co-morbidities. Based on these analyses, we recommend the modified APS-DRG system be seriously considered as an alternative to the CSA-DRGs when CMS replaces the current DRG system with an improved capability to assess patient severity.

II. Systematic Evaluation Criteria

The goal of CMS in selecting any severity adjusted DRG system is to limit the within-group variation in resource use to improve homogeneity within DRGs, and *at the same time adequately reflect an individual patient's severity*, as CMS has been tasked to do by the Medicare Payment Advisory Commission (MedPAC). The final classification system selected also needs to meet CMS' longstanding goals of administrative feasibility and transparency so that hospitals can fully understand its rules and their implications.

CMS documents and other literature discuss the following key criteria for evaluating severity-based DRG systems and the extent to which they offer the following features or enhancements to the DRG system without undue implementation burdens (see references).

- Maintaining transparency, administrative ease and public availability;
- Limiting costs of implementation and maintenance;
- Limiting manipulation potential;

- Including clinically meaningful severity assessments; and
- Enhancing ability to systematically predict resource use.

There have been a number of attempts to enhance existing DRGs ability to more precisely predict resource use by addressing differences in patient severity, to include RDRGs, SDRGs, APR-DRGs, APS-DRGs and now CSA-DRGs and the modified APS-DRGs. Each has taken a slightly different approach to this effort, resulting in different levels of potential system manipulation, system stability and implementation costs. All have involved both a statistical and clinical evaluation of the appropriateness of severity measures in an effort to ensure that the final assignments are reasonable clinically in addition to correlating to case costs (resource utilization). The greatest challenge is to develop a system that meets all of these criteria, but is also simple enough to be understood by the end users, and as transparent as possible to stakeholders with varying degrees of knowledge about patient classification systems. The system should offer administration ease and minimize added costs.

The final system should be able to be explained and understood by those using it in such a way that encourages broad support for system changes or revisions over time. This requires a fair approach that at the same time brings more accuracy to the classification system.

A. *Ensuring Transparency, Administrative Ease and Public Availability*

A critical element to incorporating severity of illness into the DRG system is ensuring that the methodology is both logical and understandable, and relatively transparent to the user. The goal of developing a system that is sophisticated, precise, and addresses as many possible differences in severity is competing with that of choosing a system which is transparent. Nonetheless, the system selected should offer a fair balance between both goals.

Transparency is of particular concern for DRG systems as DRG assignment has become more sophisticated and complex. Transparency has two dimensions:

1. For policy creation, understanding facilitates public discussion; and,
2. For program implementation, understanding facilitates both the initial implementation and long-term maintenance.

The level of transparency affects operational ease in terms of system implementation and maintenance. A higher degree of transparency will also mean that all the technical aspects of a system (for example, the DRG grouper, assignment of severity, etc) will be available to the public. This is particularly critical in ensuring that CMS can continue to engage in an on-going public dialogue regarding changes in hospital admitting practices, payments, and technology and actively seeks the participation and feedback from hospitals. In addition, being able to readily understand program rules allows coders to more appropriately and efficiently reflect resource utilization in their daily coding and management practices.

B. *Limiting Costs of Implementation and Maintenance*

Limiting costs of implementing and maintaining any changes in the DRG system, as well as keeping the impact of the changes budget neutral, remain a high priority.

CMS has already invested in development costs by engaging 3M to assess the potential use of the APR-DRGs in making its severity adjustment system. As described in more detail later in this paper, CMS has identified a way to work with the existing APR-DRGs in a consolidated fashion to adjust for severity of illness in patient DRG assignments.

Alternative proposals should not add significantly to CMS' development costs, or the costs of implementing system changes. A key system limitation which needs to be considered in any proposal needs to be the recognition that the current system can only accommodate three digit DRGs. Any increase in the number of digits required for a DRG classification would result in significant and unmanageable extra system costs at a time of increasing budgetary constraints. Second, the data required to make the severity assessments should not be significantly increased beyond what the hospitals already must identify prior to making a DRG assignment.

Both the CSA-DRGs and the APS-DRGs address these concerns in that they make use of three digit DRGs and do not require hospitals to collect different information than that already required for the current CMS DRGs. With either system, coders are likely to be more alert to properly documenting CCs, and to include secondary CCs, since they will affect the severity classifications.

Regardless of which proposal is ultimately selected, CMS will incur costs in refining the approach both before the issuance of a final rule, throughout implementation and beyond. The less significant the changes are in terms of the overall structure of the classification system, the fewer costs that will be incurred for both the government and provider community.

Because the modified APS-DRGs are an extension of the current system with the addition of a risk adjustment feature, they appear to limit implementation costs and offer greater administrative ease.

C. Limiting Manipulation Potential

Since the inception of the IPPS, policymakers have made efforts to limit the manipulation potential which any given approach has upon implementation. As the DRG system becomes more complex, any changes proposed in order to add a severity of illness adjustment to the system need to take into account the potential that such changes might lead to inappropriate manipulation. Manipulation can occur in the reporting, coding and grouping of procedures, as well as the assignment of diagnoses to improve reimbursement beyond that intended by the system.

CMS has been reluctant to implement a severity refined DRG system, in part, due to concerns about upcoding and manipulation, as occurred at inception of PPS in 1983. There is upcoding potential in both proposed systems and a certain amount of this may be unavoidable. In any event, as it has in the past, CMS always has the option to disentangle real casemix increases from "DRG creep" by reducing its rate of increase in payments accordingly in the subsequent year.

While having substantial advantages in the creation and implementation of public policy, transparency probably facilitates the manipulation of codes to increase payment. The argument is straightforward: in any system, the more one knows how inputs affect outcomes, the easier it is to select the inputs that result in the desired outcome. For this reason, APS-DRGs may be more vulnerable to manipulation. However, there is upcoding potential in both proposed systems, and this may be the price to be paid in order to achieve the benefits of more powerful severity measurements. And finally, CMS has exactly the same problem with its capitated risk adjustment system so its adaptive policies will be well formulated.

D. Clinically Meaningful Severity Assessments

Any proposal to recognize severity of illness must also be appropriate and consistent in terms of its clinical approach. The APS-DRG system has structured the clinical knowledge base into its system in a tabular form rather than through multiple series of algorithms imbedded within computer codes. The modified APS-DRGs use the same basic approach in terms of the first phases of the assignment process where clinical issues are considered.

E. Predicting Treatment Costs

In this context statistical performance has two components: the ability to explain variance (as measured by R-squared) and plausible coefficients. Regarding the latter issue, a ten percent increase, say, in casemix across hospitals should be associated with a ten percent increase in costs; that is, cost should be proportionate to casemix. Casemix should have a coefficient (or elasticity) of 1.0.

The following section compares and contrasts how each proposed severity-adjusted DRG system address the evaluation criteria set forth above.

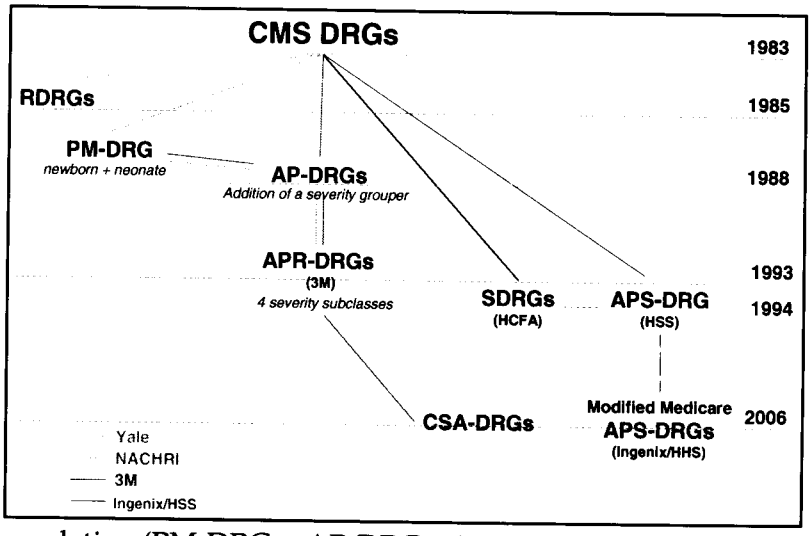
III. ASSESSMENT OF APS-DRGS AND COMPARISON TO CSA-DRGS

A. Development/Evolution of Severity-Adjusted DRGs

The Lewin Group took a number of steps to evaluate the modified APS-DRG system and compare it to the CSA-DRGs. First, we looked at the development of each in a historical context to delineate over several decades of DRG refinements, and the lineage and history of each system. While all DRG patient classification systems are designed to help appropriately predict resource use, each system offers its own combination of enhancements and limitations.

Since the inception of the original DRGs created at Yale University in the late 1960s, and the later adoption of these DRGs by Medicare in 1983, DRG refinements have resulted in a number of different systems and approaches, starting with the development of a prospective payment system to monitor resource utilization. The DRGs have been continually refined to be more useful for all patients beyond the Medicare population (PM-DRGs , AP-DRGs, APR-DRGs and APS-DRGs). ***Figure 1*** illustrates the origin of different DRGs beginning with the Medicare DRGs that were introduced into the IPPS in 1983, which are now moving into their 24th version. The figure provides a snapshot of where we are today as new severity related patient classification systems are being considered and helps to identify the links between current proposals and the systems and refinements which have developed over decades.

Figure 1: The Evolution of DRGs



Of the developers of these systems, 3M has made numerous contributions in the development of DRG technology. Recently, 3M was contracted by CMS to help develop a refined DRG system which incorporates severity measures in keeping with MedPAC's recommendations. This joint effort with CMS has resulted in a consolidated version of 3M's APR-DRG system, referred to as the CSA-DRGs, that is a part of the proposed rulemaking.

According to a Health Care Financing Administration (HCFA) document produced in 1994, the APR-DRGs were developed to address limitations in a set of refined DRGs (RDRGs) that were created by Yale.[4] RDRGs used Medicare DRGs (CMS DRGs) as their base DRGs and consequently had several drawbacks. They did not address the non-Medicare population, did not recognize the impact of multiple co-morbidities and complications (CCs), and the CC subclass was limited to the Medicare list of CCs. In addition, the structure of RDRGs included four surgical subclasses and three medical subclasses that HCFA cited in this report as inconsistent and confusing. As a result, 3M created the APR-DRGs using existing consolidated all-patient DRGs (AP-DRGs)[5] as the initial base APR-DRGs and after "a series of consolidations, additions, and modifications "[6] were made to these initial APR-DRGs, new consolidated base APR-DRGs were created. As a result of the multitude of iterations, APR-DRGs are highly complex and difficult to trace back to the original CMS DRGs. CSA-DRGs are an additional

[4] HCFA. "Refinement of the Medicare Diagnosis-Related Groups to Incorporate a Measure of Severity". June 1994.
[5] AP-DRGs were a joint effort between the New York State Department of Health and 3M in order to create a state prospective payment system for non-Medicare patients and incorporated Pediatric Modified DRGs (PM-DRGs) developed by the National Association of Children's Hospitals and Related Institutions (NACHRI) to include DRG categories for neonatal and pediatric patients.
[6] Averill, et al. "All Patient Refined Diagnosis Related Groups (APR DRGs) Methodology Review version 23.0". 3M Health Information Systems. 2006.

modification of the consolidated APR-DRGs. In the CSA-DRGs, DRGs not used by the Medicare population have been removed and some additional consolidations were made.

In an effort to address "concerns about the fairness of hospital payment and the ability of the DRG classification to adequately capture differences in levels of patient illness that impact resource consumption" HCFA introduced a new set of DRGs called severity refined DRGs (SDRGs) in 1994. They incorporated severity measures and were also known as severity-refined DRGs. These SDRGs were introduced in a manual which also included an analysis of the DRG systems at that time, particularly RDRGs and AP-DRGs. There was no analysis of the APR-DRGs, since HCFA maintained that the similarity between the APR-DRG and other systems they evaluated would produce similar results.

HCFA concluded for APR-DRGs' that "significant increase in the number of DRG classes and the resulting probability of increased low-volume DRGs and instability in relative weights from one year to the next would offset the systems' significant improvement in case-level homogeneity and ability to explain resource use for severely ill patients. In addition, the relatively complicated algorithm that [was] used [with the APR-DRGs] to determine the complexity subclass of a case is not easily explained or understood. [HCFA] believe[d] this would make it more difficult for a typical hospital to have enough experience to allow meaningful comparative analyses to be performed."[7]

These findings supported HCFA's development of SDRGs "which would incorporate aspects of both the Yale RDRGs and the New York AP-DRGs". However, the SDRGs modified the RDRGs by not automatically creating a major CC class for every DRG and, unlike the AP-DRGs, would not contain major CC DRGs on an MDC level. Instead, SDRGs consider DRGs for groups of patients with major CCs or CCs on a DRG-by-DRG basis. This resulted in a DRG classification system that included a severity measurement based on secondary diagnoses that are classified as major CCs, thereby offering the possibility of "increas[ing] DRG homogeneity, improv[ing] patient equity, and recogniz[ing] the impact of varying severity levels on resource consumption."

Building on this foundation of SDRGs, HSS, now a subsidiary of Ingenix, created an enhanced version of DRGs that considered non-Medicare patient conditions – the APS-DRGs. HSS acknowledged several problems with the SDRGs, namely they:

- Collapsed DRGs across severity levels ignoring statistically significant differences in outcomes;
- Lacked a uniform clinical structure;
- Were difficult to understand and remember; and
- Did not categorize small groups effectively, often combining them with larger groups that were not similar.

However, HSS found value in using the underlying SDRG structure of refining severity and enhanced this structure by subdividing the SDRG classification system into resource-based severity levels and corrected the problems they saw in the SDRG system in that the APS-DRGs:

[7] HCFA. "Refinement of the Medicare Diagnosis-Related Groups to Incorporate a Measure of Severity". June 2004.

- Do not aggregate severity classes within a consolidated DRG (CDRG);
- Apply an intuitive and easily explained uniform structure, based on a nationally recognized and clinically acceptable model to their DRGs;
- Revamp the current CMS newborn and neonate model based on a combination of birth weight and diagnosis;
- Go beyond the SDRG model in the handling of CC exclusion logic; and
- Support major CC exclusion logic in addition to MDC and DRG specific severity class exclusions

Additionally, HSS used the model underlying the consolidation of DRGs in SDRGs and enhanced this system by adding a risk assessment function. This resulted in a hybrid-like technology built upon the foundation of former DRG technologies and adding a component of risk adjustment discussed in further detail in the section on "Quantifying Patient Severity: Weight Setting Methodology".

Since the development of the original APS-DRGs, Ingenix, through HSS, has created the Medicare modified APS-DRGs to address the current needs of CMS. Like the original APS-DRGs, the modified APS-DRGs are a consolidated version of CMS DRGs and can easily be traced to their origins. By contrast, the CSA-DRGs have undergone several iterative processes in order to develop their base DRGs, beginning with the adoption of the AP-DRGs that are not based on the CMS DRGs that are currently in use. The value of the simplicity in origin offered by the modified APS-DRGs is that the system can be more easily understood, may be more easily implemented, and offers more flexibility in terms of adding new refinements as changes occur without resulting in complex algorithms that become opaque.

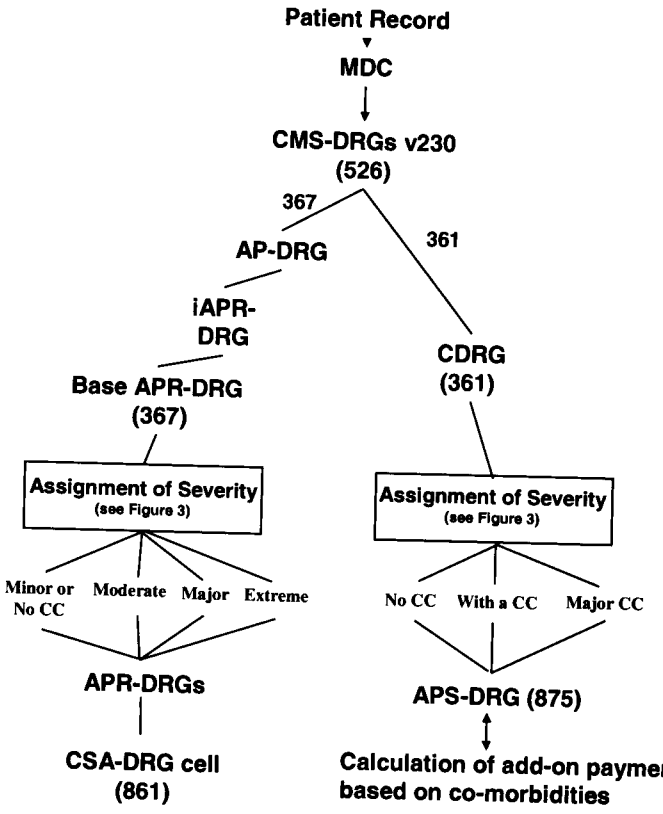
Consolidation of DRGs and Assignment of Severity Levels

The systems developed by Ingenix/HSS and 3M have methodological differences in how they consolidate DRGs and evaluate and determine severity levels. There are, however, some basic similarities in approach, starting with the way each has developed base DRGs through consolidation so they more closely reflect the Medicare patient population and volumes. They exclude those DRGs that are not relevant in a Medicare-oriented system.

Figure 2 illustrates the decision logic of the final severity and DRG assignments arrived at through each proposed methodology. The left branch of ***Figure 2*** demonstrates that the CSA-DRG proposal entails more iterations and complex algorithms following the initial identification of the base DRGs at the AP-DRG level. The diagram demonstrates the simpler approach proposed by Ingenix, on the right branch. The APS-DRGs originate directly from current CMS-DRGs which are then consolidated and, following initial severity and DRG assignments, are further modified by adding a risk adjustment factor and increasing the weight assignment based on the additional severity of the particular case based on additional independent CCs.

APS-DRG Methodology

The right branch of ***Figure 2*** illustrates APS-DRG's decision logic by mapping the process by which a final DRG is assigned and includes an additional step to reflect additional adjustments that refine the severity of the APS-DRG based on the number of additional co-morbidities.



APS -DRGs consolidate DRGs using the same underlying structure of the SDRGs as developed by HCFA, in which all DRGs with and without CCs were consolidated into "CDRGs" as identified in ***Figure 2***. In the Medicare modified version of APS-DRGs, DRGs unrelated to the Medicare population were removed. Using this methodology, HSS was able to reduce the number of CMS DRGs (526) to 361 CDRGs, reducing the total number of Medicare modified APS-DRGs to 875 (from 1,154) without compromising the system's ability to appropriately reflect resource consumption or severity. This also leaves enough additional three digit numbers open for new DRGs to be added as new technologies and treatments are developed that require system modifications.

APS-DRGs arrived at 875 total DRGS by splitting CDRGs into three resource-based severity levels: 1) no CCs, 2) with a CC, or 3) with a Major CC. Severity class is obtained by evaluating all independent secondary diagnoses of a patient, taking into account all CCs present, and resulting in a severity class that is detailed, comprehensive, and patient specific.

In addition, the APS-DRG system verifies any CDRG-specific severity class (CC) exclusions that may exist for an individual patient.

Figure 3, below, is based on 3M's assignment of severity chart as provided in the April 26, 2006 NPRM. This figure has been revised to highlight the proposed steps that modified APS-DRG and APR-DRGs (which are the basis of the proposed CSA-DRGs) have in common. Those boxes which are shared are shaded and in italics. The non-shaded boxes apply only to the APR-DRG system, which is the basis for the proposed CSA-DRGs.

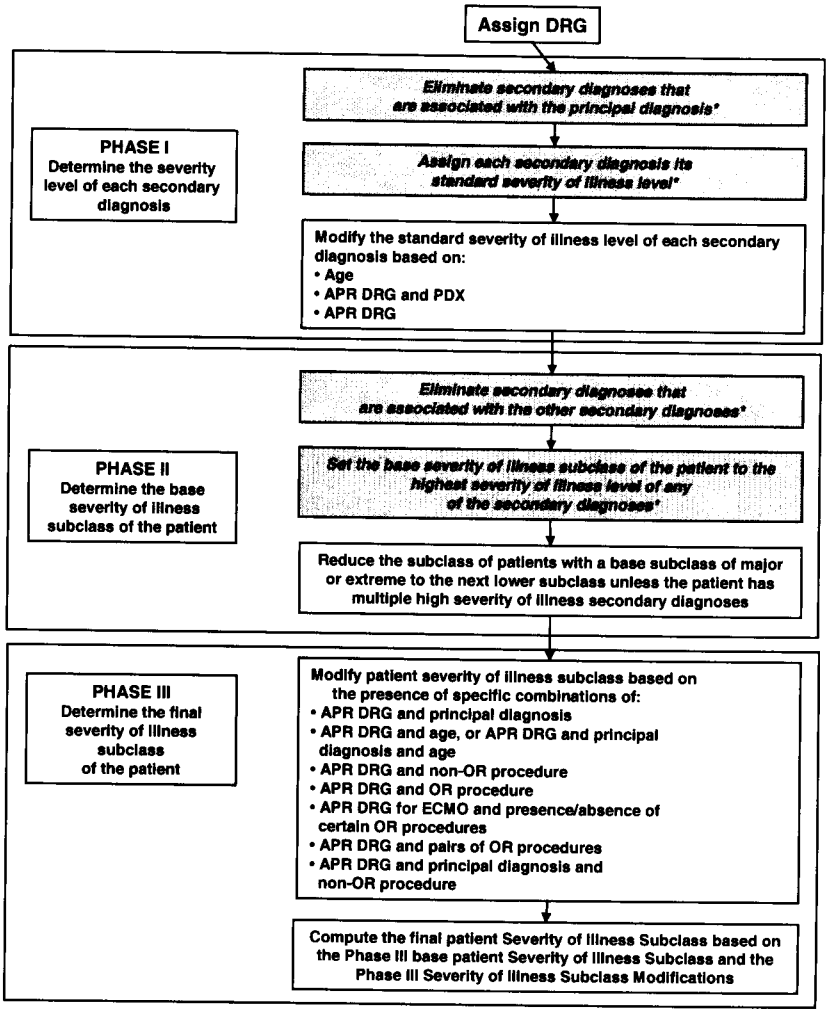
There are 19 steps involved in APS-DRGs assignment of severity (these steps are outlined in the APS-DRG Definitions Manual) prior to the risk and weight adjustments. There is no aggregation of severity classes in this model.

The Proposed Rule in the Federal Register notes that "Section 1886(d)(4) of the Act specifies that the Secretary must adjust the classifications and weighting factors at least annually to reflect changes in treatment patterns, technology, and other factors that may change the relative use of hospital resources. Therefore, we believe a method of recognizing technologies that represent increased complexity, but not necessarily greater severity of illness, should be included in the system."

Since APS-DRGs are derived directly from current CMS DRGs, they also account for complexity of procedures in the same way that current CMS DRGs do. For example, two CMS DRGs exist that differentiate between coronary angioplasty with or without stents, attributing the separate DRG to recognize the difference in complexity with the understanding that the patient may not be more severely ill. Thus, APS-DRGs reflect not only severity of illness, but also capture the complexities that exist and are already recognized through CMS' current DRGs.

The following is an example, provided by Ingenix, of how the APS-DRGs system of add-ons work:

Figure 3: Assignment of DRGs in both the APS-DRG and APR-DRG system



*Shaded boxes in italics indicate shared processes by APS-DRGs and APR-DRGs. Boxes that are unshaded indicate APR-DRG steps only.

A 73-year-old Medicare beneficiary is hospitalized with pneumonia and multiple coexisting clinical conditions as follows:

Diagnosis	Description	Status
486	Pneumonia, Organism NOS	Principal
402.91	Hypertensive Heart Disease with Failure	CC
496	Chronic Airway Obstruction NEC	CC
427.32	Atrial Flutter	CC
428	Congestive Heart Failure NOS	CC

244.9	Hypothyroidism NOS
533.9	Peptic Ulcer NOS
311	Depressive Disorder NEC

The principal diagnosis of 486 (Pneumonia) means that this case will be assigned to MDC 04, Diseases and Disorders of the Respiratory System. The first four secondary diagnoses are all considered CCs under the CMS DRG system as well as under APS-DRGs®. For this reason, the case will group to CMS DRG 089, "Simple Pneumonia and Pleurisy, Age>17, with CC." Under APS-DRGs, the case groups to 0891, which is also "Simple Pneumonia and Pleurisy, Age>17, with CC." Three (3) CCs are not used for assigning the discharge to a casemix category.

Under Medicare Modified APS-DRGs, the example changes in two ways. First, the CDRG is renamed to "Simple Pneumonia and Pleurisy" because pediatric splits have been eliminated. In addition, applying CC exclusion logic to the individual secondary diagnoses eliminates one CC from use in constructing the case-specific weight for this discharge. Specifically, 428.0 ("Congestive Heart Failure NOS") is disqualified from CC status because 402.91 ("Hypertensive Heart Disease with Failure") is also coded on the record. Modified APS-DRGs will assign this case to category 0891 with 2 independent "unused" coexisting clinical conditions with CC status.

Assume that APS-DRG 0891 has a baseline weight of 0.5258 and that each independent CC carries an adjustment factor of .23345 for medical cases in MDC 04. The final weight for this patient is 0.9927, calculated as follows:

A	Baseline Weight	0.5258
B	No. of Ind. CCs	2
C	MDC 04 Medical Adj. Factor	0.23345
A+BxC	Final Weight	0.9927

Development of APS-DRG Casemix Weights

All casemix-based payment systems need to develop a set of weights. In systems using mutually-exclusive cells (e.g., the current CMS DRGs), this process is straightforward. One simply calculates the mean cost for each cell and the mean across all cells. The ratio of the two constitutes a set of weights.

Ingenix decided that its payment for each case would be the sum of a base payment (the payment if no CCs) plus an add-on for each additional minor CC plus another add-on for each additional major CC. Therefore, if a DRG had an add-on payment of X for when a case had one major CC, its add-on payment would be 2X if a case had two major CCs.

As APS-DRGs are a hybrid system, development of its weights entails a two-step process. The first step involves calculating the weights for base payments for each DRG. These are calculated by taking the cases with no CCs and, as above, calculating the mean for each DRG.

The second step involved calculating the add-on percentage for each minor CC and major CC. Working with the cases have at least one CC, Ingenix first calculated the percent deviation as

PD = (actual cost/predicted cost) -1

where the denominator is the mean cost for a DRG as calculated in the first step. In a case-level analysis, this percent deviation is regressed on the number of minor CCs and major CCs as follows:

PD = B1*NCC + B2*NMCC

where NCC is the number of minor CCs, NMCC is the number of major CCs, and the Bs are coefficients to be estimated. (Note, the intercept was suppressed.)

Ingenix chose to run this regression separately for medical and surgical cases for each major diagnostic category (MDC). Given the tradeoff between bias and statistical power, this decision has face validity.

These parameters are used to calculate payment as follows:

W * (1 + B1*NCC + B2*NMCC) * CF

where W is the weight for the relevant DRG and CF is a conversion factor applied to all DRGs. Thus, within this MDC and medical-surgical split, there is an add-on payment of B1 percent for each minor CC and of B2 percent for each major CC.

CSA-DRG Methodology

By contrast, CSA-DRGs incorporate consolidated APR-DRGs with four complexity subclasses: 1) minor or no CC, 2) moderate, 3) major, and 4) extreme. The assignment of a patient to a subclass is a three phase process containing 18 steps. In the first phase, the complexity level of each secondary diagnosis is determined. The second phase determines a base complexity subclass for the patient based on the patient's secondary diagnoses. In the third phase, the final complexity subclass for the patient is determined by incorporating the impact of principal diagnosis, age, non-operating room (non-OR) procedures, and multiple combinations of categories of secondary diagnoses.

Further complicating severity assignment within the APR-DRG system, APR-DRGs also introduced a "re-routing logic" that "reassigns a patient to a new MDC and APR DRG in certain circumstances where the principal diagnosis is overly broad or the sequencing of principal and secondary diagnosis is unclear."[8]

This logic becomes difficult to follow given the complex algorithms used to adjust for severity, and can present difficulties for coders due to its lack of transparency. For example, without the ability to determine which codes are the most crucial to include on a hospital UB-92, hospitals who do not submit claims electronically will have no way of knowing which 9 diagnoses and 6 procedures are the most crucial to include on the forms. This lack of knowledge may result in

[8]Averill, et al. "All Patient Refined Diagnosis Related Groups (APR-DRGs) Methodology Review version 23.0". 3M Health Information Systems. 2006.

decreases in productivity across such hospitals and coders having to devote more time to identifying every possible code and choosing which to use without the decision trees and instructions that have always been available to them during the DRG assignment process.

In addition, unlike APS-DRGs, CSA-DRGs do not account for differences in complexity among different DRGs. The Proposed Rule in the Federal Register states, "If Medicare were to adopt a severity DRG system based on the APR DRG logic but assign cases based on complexity as well as severity as we do under the current Medicare DRG system, such a distinction would represent a departure from the exclusive focus on severity of illness that currently forms the basis of assigning cases in the APR DRG system."

Thus, our evaluation of the APS-DRG and APR-DRG systems indicates that APS-DRG severity assignment process offers several advantages over the complexities of the APR-DRG, and consequently, the CSA-DRG system. Assigning severity levels within the APS-DRG system is a transparent and flexible process that is translatable and able to be replicated by one choosing to understand it. This increases the chances of coders properly following program rules and being efficient in the coding process, as well as potential public acceptance of a severity-based patient classification system.

B. Comparing Transparency, Costs and Public Availability

Transparency and the corresponding ability for the public to understand and work with the system selected will be a key part in not only gaining acceptance of the new approach but also limiting implementation and maintenance costs. By continuing to offer a system that is visible and understandable to end users, CMS will be keeping an important tradition of involving the stakeholders in the development and refinement of the system to ensure it is as accurate and fair as possible.

To date, CMS has not provided adequate documentation that includes CC lists and the exclusion logic tables to allow users to fully understand the patient classification and the proposed CSA-DRG assignment process. This may be in part due to the iterative approach taken in refining the system. Some decisions appear to have been made based on different combinations of secondary diagnoses and potential exclusions that make it no longer possible to reconstruct how one might arrive at a specific DRG without using a computerized program. It is our conclusion that the CSA-DRGs are more difficult for potential users to understand than the modified APS-DRGs.

Regardless of which proposal is ultimately selected, CMS will incur some costs in refining the approach both before the issuance of a final rule and throughout implementation and beyond. The less significant the changes are in terms of the overall structure of the classification system, the fewer costs that will be incurred for both the government and provider community. The CSA-DRG system and its apparent multitude of complicated algorithms, although carefully conceived over many years of research and development, make it less transparent, flexible, or amenable to later refinement and modifications. By decreasing the amount of transparency when introducing such new systems, CMS may ultimately increase its implementation and maintenance costs beyond what might be required to implement the modified APS-DRGs.

Given the current budgetary environment, limiting costs of implementing and maintaining any changes in the DRG system, as well as keeping the impact of the changes budget neutral, remain a high priority. The modified APS-DRGs, because they are an extension of the current system with the addition of a risk adjustment feature, will likely limit implementation costs and offer greater administrative ease, as well as the ability to more easily modify and refine the system moving forward.

C. *Ability to Systematically Predict Treatment Costs*

Modified APS-DRGs perform statistically at least as well as CSA-DRGs, and both perform substantively better than the current set of DRGs.

In terms of their ability to explain variance, modified APS-DRGs perform at least as well as CSA-DRGs and, in fact, slightly better. This is true at both the case level and hospital level. (See the table for the regression results and the appendix for a discussion of the underlying methodology used by The Lewin Group in its analysis.)

At the hospital level, the casemix coefficient is higher than 1.0 (and statistically significant) for all three casemix systems. It is 1.36 for the current set of CMS DRGs, 1.20 CSA-DRGs, and 1.07 for the modified APS-DRGs. Because IPPS payment is proportionate to casemix but the regression implies a more-than-proportionate relationship between cost and casemix, high-casemix hospitals are being underpaid relative to low-casemix ones, even after accounting for the add-on payments for teaching and disproportionate share percentage. This problematic pattern would be substantially greater under CSA-DRGs than under modified APS-DRGs.

There are several possible explanations for this pattern of greater-than-proportionate relationship between cost and casemix. First, this hospital-level finding is consistent with "compression," an important issue in all payment systems. The concern here is that the DRG weights are too low for expensive DRGs and too high for inexpensive DRGs, such that the range of payment is "compressed." However, the casemix coefficient is about 1.0 in case-level regressions for all three DRG systems, suggesting that weights themselves are not the problem here.

More plausibly, within a given DRG (or more precisely, within a payment category), high-casemix hospitals have more expensive patients than low-casemix hospitals. This could result from either:

- Heterogeneity of severity within each payment category, with higher mean for high-casemix hospitals; or
- Some other factor that is correlated with having a high casemix. For instance, the payment mechanism has not controlled for all aspects of teaching hospitals.

However, the fact that the greater-than-proportionate pattern is greatly diminished with modified APS-DRGs suggests that its cause is within-payment-category heterogeneity for the current DRGs and CSA-DRGs. Thus, CSA-DRGs would underpay high-casemix hospitals substantially more than APS-DRGs.

In sum, modified APS-DRGs explain at least as much variance as CSA-DRGs and would underpay high-casemix hospitals substantially less.

IV. CONCLUSION

Irrespective of which system CMS eventually chooses to improve its ability to reflect severity, it is incumbent upon CMS to make the grouper logic transparent and publicly available at a minimal cost. This will encourage on-going public discussion and open evaluation of the potential alternatives prior to the final adoption of a severity adjusted DRG system.

After a careful assessment, The Lewin Group has concluded that the modified APS-DRGs are worthy of consideration by CMS and the general public as an alternative to the proposed CSA-DRGs. They offer a simpler, more transparent, and perhaps more accurate approach by essentially extending CMS' approach to DRGs to date and adding the value of the CMS risk adjustment methodologies already used for capitated and psychiatric services to all DRG severity weight assignments. APS-DRGs are statistically sound, offer system stability and flexibility over time, and are both precise and comprehensive.

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Appendix A: Methodology of Regression of Cost on Casemix Measures

For each of the three casemix measures considered here, The Lewin Group regressed cost-per-case on the casemix weight to investigate two questions:

- Would hospitals be paid fairly? That is, would average payment to a hospital (across all its cases) be closely related to its average costs?
- Would payment for each case be closely related to its cost? Here the issue is not fairness per se but rather the potential for "cherry-picking," the potential for a hospital to design policies that would result in a disproportionate percentage of cases that were less expensive to treat than others receiving the payment rate?

To address the hospital-level fairness issue, we performed a hospital-level regression analysis. We examine the "cherry-picking" issue by conducting a case-level regression analysis.

Data

We obtained case-level charge data from 2004 MedPAR (Medicare Provider Analysis and Review) file. From the Medicare Inpatient Impact File, we obtained the cost-to-charge ratios (for operating and capital expenses), CSA-DRG weight, and several variables used to calculate Medicare's payment:

Wage = wage index used under IPPS,
COLA = cost-of-living adjustment (COLA, which equals 1.0 for all states except Alaska and Hawaii),
IRB = payment adjustment factor for teaching hospitals, and
DSH = payment adjustment factor for disproportionate share (DSH) hospitals.

From the Impact File also came:

two cost-to-charge ratios:
Ratio of operating costs to total covered charges and
Ratio of capital costs to total covered charges,

and two outlier variables:
Out_op = operating outlier payments as a percentage of operating IPPS payments and
Out_cap = capital outlier payments as a percentage of capital IPPS payments.

Ingenix/HSS calculated the casemix weight for each case for the current CMS DRG and the modified APS-DRG.

The cost for each case was calculated as the covered charges times the sum of the two charge ratios.

The case-level file was aggregated to the hospital level, with variables for cost per case and weight per case (i.e., casemix index).

Specification

Regressions of cost on casemix typically take one of two forms. In "payment regressions," cost per case is standardized for payment variables (other than casemix) before being regressed on casemix index. In "explanatory regressions," cost per case is regressed on casemix index and other variables related to payment. Both forms of regressions may include variables that are unrelated to payment.

As the conclusions drawn from the two sets of regression are the same, we present only the results for the payment regressions, as they are the simpler of the two.

Cost per case was standardized as follows:

Cost/ [(.70*wage + .30*COLA) (1 + IRB + DSH)].

Although outliers affect payment, there is no straight-forward way to use them to standardize cost.

A double-log regression was used, so the log of standardized cost per case was regressed on the log of casemix. The logarithms of each of the two outlier percentage variables (plus one) were also entered in this regression. So the regression was specified as follows:

Log(standardized cost per case) = B0 + B1*log(casemix index) +
B2*log(out_op+1) +B3*log(out_cap+1)

Alternative Casemix Measures as Predictors of Cost-per-Case Standardized by Payment Variables: Hospital and Case Levels

		Hospital Level			Case Level		
		CMS DRGs	CSA-DRGs	APS-DRGs	CMS DRGs	CSA-DRGs	APS-DRGs
Casemix							
	CMS DRGs	1.360			0.981		
		(41.20)			(2927.49)		
	CSA-DRGs		1.203			0.977	
			(44.08)			(3453.17)	
	APS-DRGs			1.072			0.974
				(46.11)			(3551.14)
Outlier % of payment							
	Operating	0.39	0.33	0.52	0.89	0.70	0.73
		(2.68)	(2.35)	(3.78)	(143.24)	(121.82)	(128.29)
	Capital	0.54	0.56	0.50	0.43	0.44	0.44
		(4.54)	(4.83)	(4.33)	(82.50)	(90.05)	(91.98)
Intercept		8.41	8.50	8.55	8.65	8.70	8.71
R-square		0.419	0.446	0.464	0.436	0.517	0.530
F		812.7	906.4	976.4	>1m	>1m	>1m
N		3389	3389	3389	11.6m	11.6m	11.6m

m = million. "CMS DRGs" are the DRGs currently used by CMS. APS-DRGs have been modified for Medicare. T-values are in parentheses. All variables are in logarithmic form.
Source: MedPAC and Impact Files.

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July 12, 2006

Mark B. McClellan, Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Room 445-G
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Administrator McClellan:

Ingenix submitted extensive comments in response to the Centers for Medicare and Medicaid Services proposed rule related to the fiscal year 2007 inpatient hospital prospective payment system. As a follow up to that correspondence, we want to make sure you are directly aware of our offer to provide the All-Payer Severity-adjusted DRG reimbursement methodology ("APS-DRGs"), which was developed by Ingenix, free of charge to CMS and to provide it to the industry in an open and transparent fashion as a utility.

The independent and highly respected Lewin Group has conducted a study comparing the APS-DRG system as an alternative methodology to the newly proposed consolidated severity-adjusted system (CSA-DRGs). The Lewin evaluation concludes that Ingenix's modified APS-DRGs are simpler and more flexible than CSA-DRGs. As a result, the APS-DRGs are likely to be more transparent, easier for hospitals to implement, and easier to maintain and improve over time than CSA-DRGs. The Lewin Group further found that APS-DRGs explain at least as much variance in patient severity as CSA-DRGs and are less likely to underpay high-casemix hospitals than CSA-DRGs. Attached is a copy of the full Lewin study.

We look forward to meeting with you in person to discuss our concerns related to the proposed rule as well as to discuss the APS-DRG methodology which we believe deserves serious consideration by CMS and the general public as an alternative to the proposed CSA-DRGs.

Thank you for your time and attention.

Sincerely,

Richard Anderson

The LEWIN GROUP

An Evaluation of APS-DRGs In Comparison to the Newly Proposed CSA-DRGs

Final Report

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June 12, 2006

TABLE OF CONTENTS

EXECUTIVE SUMMARY

The fairness and efficiency of Medicare's system of paying acute care hospitals depends, in part, on the system's ability to distinguish cases according to the patient's severity of illness. To better meet this objective, the Centers for Medicare and Medicaid Services (CMS) proposed using consolidated severity-adjusted DRGs (CSA-DRGs) in its Notice of Proposed Rulemaking (NPRM) dated April 25, 2006. Ingenix has developed the Medicare modified all patient-severity DRGs (or "modified APS-DRGs")[1] and proposes that CMS formally consider APS-DRGs as an alternative to the CSA-DRGs. The Lewin Group was engaged by Ingenix to conduct an independent evaluation of its APS-DRG system in comparison to CSA-DRGs.

As part of this evaluation, we reviewed the documentation for the two systems, examined the NPRM and descriptions of earlier systems, and performed a series of comparative regression analyses. Our evaluation was constrained by the extent of the information available on APR-DRG grouping logic and by the inherent time constraints associated with responding to proposed rulemaking.

Primary Assessment

After evaluation, The Lewin Group concluded that Ingenix's modified APS-DRGs are fundamentally simpler and more flexible than CSA-DRGs. Because of this simplicity and flexibility, the modified APS-DRGs may be more transparent, easier for hospitals to implement, and easier to maintain and improve over time than CSA-DRGs. Furthermore, the Lewin Group found that APS-DRGs explain at least as much variance in patient case costs as CSA-DRGs and are less likely to underpay high-casemix hospitals than CSA-DRGs.

APS-DRGs are a hybrid of two analytic systems already in use by CMS:

- Each case is assigned to one and only one cell (i.e. DRG) [2]; and
- Within a cell, a case may involve an add-on payment that reflects the case's greater than average severity. This add-on payment amount is calculated via regression analysis as with CMS' current risk adjustment systems.

APS-DRGs build on CMS' current co-morbidity conditions and complications (CC) listings and exclusion logic but recognize the differences in severity among patients. On the one hand, this represents a paradigm shift in patient categorization methodology for acute care hospital payments - one that better reflects varying levels of severity for inpatients within DRG based cells. On the other hand, CMS currently uses similar systems to pay psychiatric hospitals and managed care organizations.

The goal of CMS in selecting a severity adjusted DRG system is to limit the within-group variation in resource use to improve homogeneity within DRGs, and, at the same time, adequately reflect an individual patient's severity, as CMS has been tasked to do by the

[1] The original APS-DRGs were developed by HHS, Inc., which was acquired by Ingenix in May 2005. The APS-DRG system has been modified for the Medicare population.

[2] The current DRG system does have an add-on payment for technology but no add-on payment for severity.

Medicare Payment Advisory Commission (MedPAC). The final classification system selected also needs to meet CMS' longstanding goals of administrative feasibility and transparency so that hospitals can fully understand its expectations and rules.

CMS documents and other key literature discuss the following key criteria for evaluating severity-based DRG systems and the extent to which they offer the following features or enhancements to the DRG system without undue implementation burdens (see references).

- Maintaining transparency, administrative ease and public availability;
- Limiting costs of implementation and maintenance;
- Limiting manipulation potential;
- Including clinically meaningful severity assessments; and
- Enhancing ability to systematically predict resource use.

Transparency, Administrative Ease and Public Availability

Transparency is an issue that occurs across many aspects of government and some aspects of business. In a democracy, transparency (i.e., publicly available information) is considered desirable except in special exceptions. For instance, under the Freedom of Information Act (FOIA), citizens can obtain information on a wide range of topics, but not all (e.g., personnel matters). CMS payment policies have generally been transparent.

In the case of DRGs, transparency results in an understanding of the logic of DRG systems, which is important for two reasons:

1. For policy creation, understanding facilitates public discussion; and,
2. For program implementation, understanding facilitates both the initial implementation and long-term maintenance.

Unlike the proposed CSA-DRGs, each component of the modified APS-DRG system can be readily examined. The first part of the hybrid system incorporates the existing CC listings and exclusion logic, which are already publicly available. The second part involves an add-on payment for each additional comorbidity. Understanding the general approach does not require a detailed knowledge of medical conditions and coding. While there undoubtedly are subtleties, analysts will be able to quickly understand the basic logic of this approach.

To date, CMS has not provided adequate documentation (e.g., CC lists and the exclusion logic tables) to allow users to fully understand the CSA-DRG assignment process. This may be, in part, due to the iterative approach taken in refining the system. Because some cases are assigned to a given CSA-DRG, apparently based on different combinations of secondary diagnoses and potential exclusions, one cannot reconstruct (i.e., reverse engineer) the assignment algorithm from the DRG assignment of specific cases. It is our conclusion that the CSA-DRGs are more difficult for potential users to understand than the modified APS-DRGs. Transparency is a critical concern as DRG assignment has become more sophisticated and complex.

A higher degree of transparency will also mean that all the technical aspects of a system (for example, the DRG grouper, assignment of severity, etc.) will be available to the public. This is particularly critical in ensuring CMS can continue to engage in an on-going public dialogue regarding changes in hospital admitting practices, payments, and technology and actively seeks the participation and feedback from hospitals. Being able to readily understand program rules allows coders to more appropriately and efficiently reflect resource utilization in their every day coding and management practices.

Limiting Costs of Implementation and Maintenance

Regardless of the severity system ultimately selected, CMS will incur costs in refining the approach before the issuance of a final rule, throughout implementation, and beyond. The less significant the changes are in terms of the overall structure of the classification system, the fewer costs that will be incurred for both the government and provider community. The CSA-DRG system and its complex algorithms, although based on APR-DRGs which have been carefully conceived over many years of research and development, make it less transparent, flexible or amenable to later refinement and modifications. By forgoing transparency when introducing such new systems, CMS may ultimately increase its implementation and maintenance costs beyond what might be required to implement the modified APS-DRGs.

Manipulation Potential

Another key concern of policymakers, since the inception of the IPPS, has been to limit manipulation potential which any system is vulnerable during implementation. As the DRG system becomes more complex, changes proposed to add a severity of illness adjustment to the system should account for the potential for inappropriate manipulation in reporting, coding, and grouping procedures, as well as assigning diagnoses to improve reimbursement beyond that intended by the system.

Part of the reason CMS has been reluctant to implement a severity refined DRG system is a fear of upcoding and manipulation, as occurred at the inception of the IPPS in 1983. The more transparent the system, the easier the system will be to manipulate, since the results that coding will produce will be clear. However, there is upcoding potential in both proposed systems, and this may be the price to be paid in order to achieve the benefits of more powerful severity measurements. In any event, CMS, as it has in the past, always has the option to disentangle real casemix increases from "DRG creep" by reducing the rate of increase accordingly in the subsequent year. And finally, CMS has exactly the same problem with its capitated risk adjustment system so its adaptive policies will be well formulated.

Clinically Meaningful

Any proposed new approach to recognize severity of illness must also be appropriate and consistent in terms of its clinical approach. The APS-DRG system has structured the clinical knowledge base into its system in a tabular form; conversely, the CSA-DRG system requires multiple decision rules imbedded in computer codes. The modified APS-DRGs use the same basic approach in terms of the first phases of the assignment process where clinical issues are explicitly considered.

Systematically Predicting Treatment Cost

The two casemix systems use approximately the same number of DRGs. However, only the APS-DRG system includes an add-on to the weights (and hence payments) that recognizes the number of independent comorbidities. Because of this second component, we hypothesized that APS-DRGs predict treatment cost (or resource utilization) better than CSA-DRGs. We test this hypothesis as part of our analyses.

The more accurately a casemix system predicts resource use, the better suited it is to support payment. In this context statistical performance has two components: the ability to explain variance (as measured by R-squared) and plausible coefficients. Regarding the latter issue, a ten percent increase, for instance, in casemix across hospitals should be associated with a ten percent increase in cost; that is, cost should have an elasticity of 1.0 with respect to casemix.

To assess these casemix systems, we performed regression analyses using 2004 Medicare MedPAR data. Cost, standardized for payment variables, was regressed on the various casemix measures. [3] From the results, we drew two conclusions. First, modified APS-DRGs explain at least as much variance as CSA-DRGs. Second, costs have elasticity above 1.0 with respect to CSA-DRGs but only slightly above 1.0 for APS-DRGs, so both systems would underpay high-casemix hospitals. However, the problem is substantially less under APS-DRGs.

Conclusion

After a careful assessment, The Lewin Group has concluded that the modified APS-DRGs are worthy of consideration by CMS and the public policy community as an alternative to the proposed CSA-DRGs. The modified APS-DRGs offer a simpler, more transparent, and perhaps more accurate approach by essentially extending CMS' current approach to DRGs and adding the value of risk adjustment type methodologies. CMS already uses this hybrid methodology to pay psychiatric hospitals and managed care organizations. We found that APS-DRGs are statistically sound.

CMS has traditionally made its payment policies transparent. Regardless of what system CMS implements, we urge it continue this tradition by making the grouper logic entirely transparent and publicly available at minimal cost.

[3] In one of its publicly available datasets, CMS has applied the CSA-DRG software to all the discharges in 2004. We had access to this dataset, not to the algorithm.

I. Background and Purpose

On April 25, 2006, the Centers for Medicare & Medicaid Services (CMS) issued proposed changes to the Medicare hospital inpatient prospective payment system (IPPS) based on the recommendations provided by the Medicare Payment Advisory Committee (MedPAC). These recommendations included the addition of severity of illness refinements to current diagnosis related groups (DRGs) and the application of hospital-specific relative value (HSRV) weights to DRGs in order to increase the accuracy of Medicare payments and prevent hospitals from "cherry picking" cases that would be the most profitable.

The proposed consolidated severity-adjusted DRGs (CSA-DRGs) are a version of 3M's current all patient-refined DRGs (APR-DRGs), currently used by the State of Maryland for hospital payment and by a number of other state health information agencies and other organizations for quality monitoring. In the proposed rule, CMS has requested "public comments on whether there are alternative DRG systems that could result in better recognition of severity than the consolidated severity-adjusted DRGs" they are proposing.

The Lewin Group was engaged by Ingenix to conduct an independent evaluation of its proposed alternative to the CSA-DRGs - the modified APS-DRGs. In this paper, we discuss the findings of our evaluation and the methods through which we compared the modified APS-DRGs to the CSA-DRGs. We present evaluation criteria, describe the origins and approach of each system, and describe how the systems compare to each other. We then provide a qualitative and quantitative assessment of the modified APS-DRGs and the unique system they have developed to assign individual patient weights which takes into account both casemix and adds risk adjustments for additional independent co-morbidities. Based on these analyses, we recommend the modified APS-DRG system be seriously considered as an alternative to the CSA-DRGs when CMS replaces the current DRG system with an improved capability to assess patient severity.

II. Systematic Evaluation Criteria

The goal of CMS in selecting any severity adjusted DRG system is to limit the within-group variation in resource use to improve homogeneity within DRGs, and *at the same time adequately reflect an individual patient's severity*, as CMS has been tasked to do by the Medicare Payment Advisory Commission (MedPAC). The final classification system selected also needs to meet CMS' longstanding goals of administrative feasibility and transparency so that hospitals can fully understand its rules and their implications.

CMS documents and other literature discuss the following key criteria for evaluating severity-based DRG systems and the extent to which they offer the following features or enhancements to the DRG system without undue implementation burdens (see references).

- Maintaining transparency, administrative ease and public availability;
- Limiting costs of implementation and maintenance;
- Limiting manipulation potential;

- Including clinically meaningful severity assessments; and
- Enhancing ability to systematically predict resource use.

There have been a number of attempts to enhance existing DRGs ability to more precisely predict resource use by addressing differences in patient severity, to include RDRGs, SDRGs, APR-DRGs, APS-DRGs and now CSA-DRGs and the modified APS-DRGs. Each has taken a slightly different approach to this effort, resulting in different levels of potential system manipulation, system stability and implementation costs. All have involved both a statistical and clinical evaluation of the appropriateness of severity measures in an effort to ensure that the final assignments are reasonable clinically in addition to correlating to case costs (resource utilization). The greatest challenge is to develop a system that meets all of these criteria, but is also simple enough to be understood by the end users, and as transparent as possible to stakeholders with varying degrees of knowledge about patient classification systems. The system should offer administration ease and minimize added costs.

The final system should be able to be explained and understood by those using it in such a way that encourages broad support for system changes or revisions over time. This requires a fair approach that at the same time brings more accuracy to the classification system.

A. Ensuring Transparency, Administrative Ease and Public Availability

A critical element to incorporating severity of illness into the DRG system is ensuring that the methodology is both logical and understandable, and relatively transparent to the user. The goal of developing a system that is sophisticated, precise, and addresses as many possible differences in severity is competing with that of choosing a system which is transparent. Nonetheless, the system selected should offer a fair balance between both goals.

Transparency is of particular concern for DRG systems as DRG assignment has become more sophisticated and complex. Transparency has two dimensions:

1. For policy creation, understanding facilitates public discussion; and,
2. For program implementation, understanding facilitates both the initial implementation and long-term maintenance.

The level of transparency affects operational ease in terms of system implementation and maintenance. A higher degree of transparency will also mean that all the technical aspects of a system (for example, the DRG grouper, assignment of severity, etc) will be available to the public. This is particularly critical in ensuring that CMS can continue to engage in an on-going public dialogue regarding changes in hospital admitting practices, payments, and technology and actively seeks the participation and feedback from hospitals. In addition, being able to readily understand program rules allows coders to more appropriately and efficiently reflect resource utilization in their daily coding and management practices.

B. Limiting Costs of Implementation and Maintenance

Limiting costs of implementing and maintaining any changes in the DRG system, as well as keeping the impact of the changes budget neutral, remain a high priority.

CMS has already invested in development costs by engaging 3M to assess the potential use of the APR-DRGs in making its severity adjustment system. As described in more detail later in this paper, CMS has identified a way to work with the existing APR-DRGs in a consolidated fashion to adjust for severity of illness in patient DRG assignments.

Alternative proposals should not add significantly to CMS' development costs, or the costs of implementing system changes. A key system limitation which needs to be considered in any proposal needs to be the recognition that the current system can only accommodate three digit DRGs. Any increase in the number of digits required for a DRG classification would result in significant and unmanageable extra system costs at a time of increasing budgetary constraints. Second, the data required to make the severity assessments should not be significantly increased beyond what the hospitals already must identify prior to making a DRG assignment.

Both the CSA-DRGs and the APS-DRGs address these concerns in that they make use of three digit DRGs and do not require hospitals to collect different information than that already required for the current CMS DRGs. With either system, coders are likely to be more alert to properly documenting CCs, and to include secondary CCs, since they will affect the severity classifications.

Regardless of which proposal is ultimately selected, CMS will incur costs in refining the approach both before the issuance of a final rule, throughout implementation and beyond. The less significant the changes are in terms of the overall structure of the classification system, the fewer costs that will be incurred for both the government and provider community.

Because the modified APS-DRGs are an extension of the current system with the addition of a risk adjustment feature, they appear to limit implementation costs and offer greater administrative ease.

C. Limiting Manipulation Potential

Since the inception of the IPPS, policymakers have made efforts to limit the manipulation potential which any given approach has upon implementation. As the DRG system becomes more complex, any changes proposed in order to add a severity of illness adjustment to the system need to take into account the potential that such changes might lead to inappropriate manipulation. Manipulation can occur in the reporting, coding and grouping of procedures, as well as the assignment of diagnoses to improve reimbursement beyond that intended by the system.

CMS has been reluctant to implement a severity refined DRG system, in part, due to concerns about upcoding and manipulation, as occurred at inception of PPS in 1983. There is upcoding potential in both proposed systems and a certain amount of this may be unavoidable. In any event, as it has in the past, CMS always has the option to disentangle real casemix increases from "DRG creep" by reducing its rate of increase in payments accordingly in the subsequent year.

While having substantial advantages in the creation and implementation of public policy, transparency probably facilitates the manipulation of codes to increase payment. The argument is straightforward: in any system, the more one knows how inputs affect outcomes, the easier it is to select the inputs that result in the desired outcome. For this reason, APS-DRGs may be more vulnerable to manipulation. However, there is upcoding potential in both proposed systems, and this may be the price to be paid in order to achieve the benefits of more powerful severity measurements. And finally, CMS has exactly the same problem with its capitated risk adjustment system so its adaptive policies will be well formulated.

D. Clinically Meaningful Severity Assessments

Any proposal to recognize severity of illness must also be appropriate and consistent in terms of its clinical approach. The APS-DRG system has structured the clinical knowledge base into its system in a tabular form rather than through multiple series of algorithms imbedded within computer codes. The modified APS-DRGs use the same basic approach in terms of the first phases of the assignment process where clinical issues are considered.

E. Predicting Treatment Costs

In this context statistical performance has two components: the ability to explain variance (as measured by R-squared) and plausible coefficients. Regarding the latter issue, a ten percent increase, say, in casemix across hospitals should be associated with a ten percent increase in costs; that is, cost should be proportionate to casemix. Casemix should have a coefficient (or elasticity) of 1.0.

The following section compares and contrasts how each proposed severity-adjusted DRG system address the evaluation criteria set forth above.

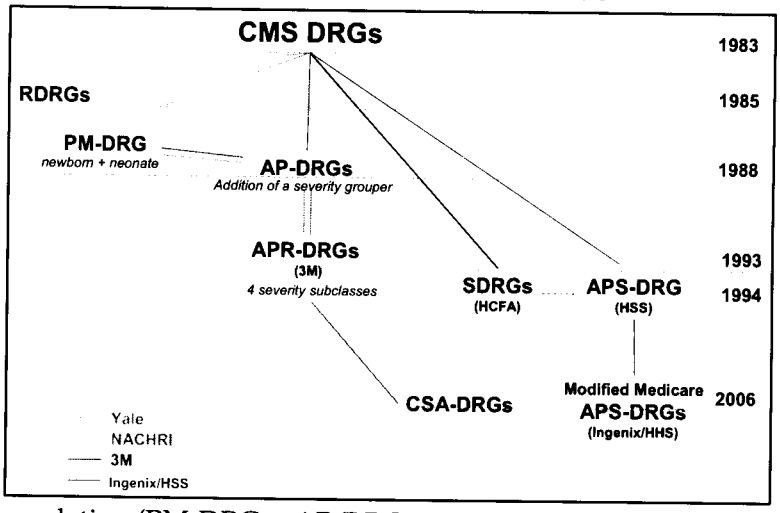
III. ASSESSMENT OF APS-DRGS AND COMPARISON TO CSA-DRGS

A. Development/Evolution of Severity-Adjusted DRGs

The Lewin Group took a number of steps to evaluate the modified APS-DRG system and compare it to the CSA-DRGs. First, we looked at the development of each in a historical context to delineate over several decades of DRG refinements, and the lineage and history of each system. While all DRG patient classification systems are designed to help appropriately predict resource use, each system offers its own combination of enhancements and limitations.

Since the inception of the original DRGs created at Yale University in the late 1960s, and the later adoption of these DRGs by Medicare in 1983, DRG refinements have resulted in a number of different systems and approaches, starting with the development of a prospective payment system to monitor resource utilization. The DRGs have been continually refined to be more useful for all patients beyond the Medicare population (PM-DRGs , AP-DRGs, APR-DRGs and APS-DRGs). ***Figure 1*** illustrates the origin of different DRGs beginning with the Medicare DRGs that were introduced into the IPPS in 1983, which are now moving into their 24th version. The figure provides a snapshot of where we are today as new severity related patient classification systems are being considered and helps to identify the links between current proposals and the systems and refinements which have developed over decades.

Figure 1: The Evolution of DRGs



Of the developers of these systems, 3M has made numerous contributions in the development of DRG technology. Recently, 3M was contracted by CMS to help develop a refined DRG system which incorporates severity measures in keeping with MedPAC's recommendations. This joint effort with CMS has resulted in a consolidated version of 3M's APR-DRG system, referred to as the CSA-DRGs, that is a part of the proposed rulemaking.

According to a Health Care Financing Administration (HCFA) document produced in 1994, the APR-DRGs were developed to address limitations in a set of refined DRGs (RDRGs) that were created by Yale.[4] RDRGs used Medicare DRGs (CMS DRGs) as their base DRGs and consequently had several drawbacks. They did not address the non-Medicare population, did not recognize the impact of multiple co-morbidities and complications (CCs), and the CC subclass was limited to the Medicare list of CCs. In addition, the structure of RDRGs included four surgical subclasses and three medical subclasses that HCFA cited in this report as inconsistent and confusing. As a result, 3M created the APR-DRGs using existing consolidated all-patient DRGs (AP-DRGs)[5] as the initial base APR-DRGs and after "a series of consolidations, additions, and modifications "[6] were made to these initial APR-DRGs, new consolidated base APR-DRGs were created. As a result of the multitude of iterations, APR-DRGs are highly complex and difficult to trace back to the original CMS DRGs. CSA-DRGs are an additional

[4] HCFA. "Refinement of the Medicare Diagnosis-Related Groups to Incorporate a Measure of Severity". June 1994.

[5] AP-DRGs were a joint effort between the New York State Department of Health and 3M in order to create a state prospective payment system for non-Medicare patients and incorporated Pediatric Modified DRGs (PM-DRGs) developed by the National Association of Children's Hospitals and Related Institutions (NACHRI) to include DRG categories for neonatal and pediatric patients.

[6] Averill, et al. "All Patient Refined Diagnosis Related Groups (APR DRGs) Methodology Review version 23.0". 3M Health Information Systems. 2006.

modification of the consolidated APR-DRGs. In the CSA-DRGs, DRGs not used by the Medicare population have been removed and some additional consolidations were made.

In an effort to address "concerns about the fairness of hospital payment and the ability of the DRG classification to adequately capture differences in levels of patient illness that impact resource consumption" HCFA introduced a new set of DRGs called severity refined DRGs (SDRGs) in 1994. They incorporated severity measures and were also known as severity-refined DRGs. These SDRGs were introduced in a manual which also included an analysis of the DRG systems at that time, particularly RDRGs and AP-DRGs. There was no analysis of the APR-DRGs, since HCFA maintained that the similarity between the APR-DRG and other systems they evaluated would produce similar results.

HCFA concluded for APR-DRGs' that "significant increase in the number of DRG classes and the resulting probability of increased low-volume DRGs and instability in relative weights from one year to the next would offset the systems' significant improvement in case-level homogeneity and ability to explain resource use for severely ill patients. In addition, the relatively complicated algorithm that [was] used [with the APR-DRGs] to determine the complexity subclass of a case is not easily explained or understood. [HCFA] believe[d] this would make it more difficult for a typical hospital to have enough experience to allow meaningful comparative analyses to be performed."[7]

These findings supported HCFA's development of SDRGs "which would incorporate aspects of both the Yale RDRGs and the New York AP-DRGs". However, the SDRGs modified the RDRGs by not automatically creating a major CC class for every DRG and, unlike the AP-DRGs, would not contain major CC DRGs on an MDC level. Instead, SDRGs consider DRGs for groups of patients with major CCs or CCs on a DRG-by-DRG basis. This resulted in a DRG classification system that included a severity measurement based on secondary diagnoses that are classified as major CCs, thereby offering the possibility of "increas[ing] DRG homogeneity, improv[ing] patient equity, and recogniz[ing] the impact of varying severity levels on resource consumption."

Building on this foundation of SDRGs, HSS, now a subsidiary of Ingenix, created an enhanced version of DRGs that considered non-Medicare patient conditions - the APS-DRGs. HSS acknowledged several problems with the SDRGs, namely they:

- Collapsed DRGs across severity levels ignoring statistically significant differences in outcomes;
- Lacked a uniform clinical structure;
- Were difficult to understand and remember; and
- Did not categorize small groups effectively, often combining them with larger groups that were not similar.

However, HSS found value in using the underlying SDRG structure of refining severity and enhanced this structure by subdividing the SDRG classification system into resource-based severity levels and corrected the problems they saw in the SDRG system in that the APS-DRGs:

[7] HCFA. "Refinement of the Medicare Diagnosis-Related Groups to Incorporate a Measure of Severity". June 2004.

- Do not aggregate severity classes within a consolidated DRG (CDRG);
- Apply an intuitive and easily explained uniform structure, based on a nationally recognized and clinically acceptable model to their DRGs;
- Revamp the current CMS newborn and neonate model based on a combination of birth weight and diagnosis;
- Go beyond the SDRG model in the handling of CC exclusion logic; and
- Support major CC exclusion logic in addition to MDC and DRG specific severity class exclusions

Additionally, HSS used the model underlying the consolidation of DRGs in SDRGs and enhanced this system by adding a risk assessment function. This resulted in a hybrid-like technology built upon the foundation of former DRG technologies and adding a component of risk adjustment discussed in further detail in the section on "Quantifying Patient Severity: Weight Setting Methodology".

Since the development of the original APS-DRGs, Ingenix, through HSS, has created the Medicare modified APS-DRGs to address the current needs of CMS. Like the original APS-DRGs, the modified APS-DRGs are a consolidated version of CMS DRGs and can easily be traced to their origins. By contrast, the CSA-DRGs have undergone several iterative processes in order to develop their base DRGs, beginning with the adoption of the AP-DRGs that are not based on the CMS DRGs that are currently in use. The value of the simplicity in origin offered by the modified APS-DRGs is that the system can be more easily understood, may be more easily implemented, and offers more flexibility in terms of adding new refinements as changes occur without resulting in complex algorithms that become opaque.

Consolidation of DRGs and Assignment of Severity Levels

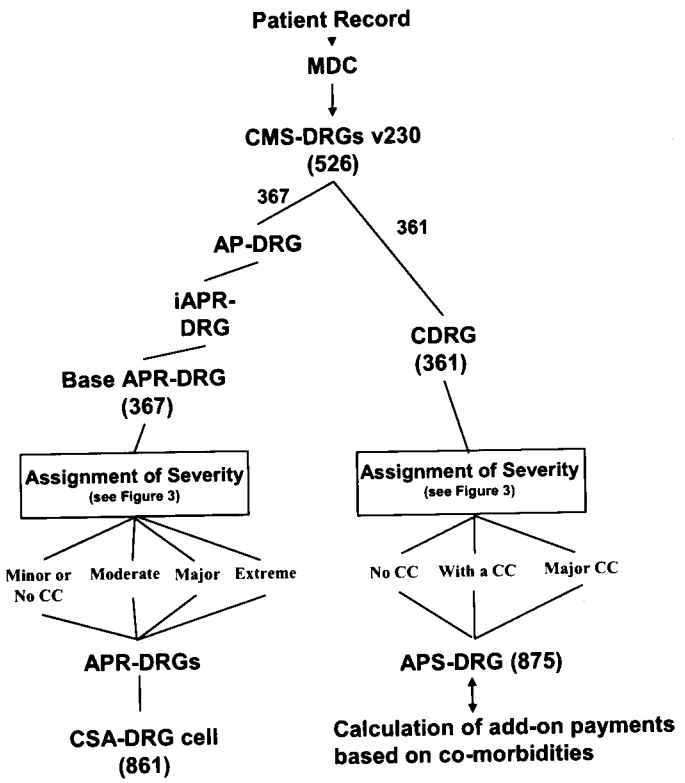
The systems developed by Ingenix/HSS and 3M have methodological differences in how they consolidate DRGs and evaluate and determine severity levels. There are, however, some basic similarities in approach, starting with the way each has developed base DRGs through consolidation so they more closely reflect the Medicare patient population and volumes. They exclude those DRGs that are not relevant in a Medicare-oriented system.

Figure 2 illustrates the decision logic of the final severity and DRG assignments arrived at through each proposed methodology. The left branch of ***Figure 2*** demonstrates that the CSA-DRG proposal entails more iterations and complex algorithms following the initial identification of the base DRGs at the AP-DRG level. The diagram demonstrates the simpler approach proposed by Ingenix, on the right branch. The APS-DRGs originate directly from current CMS-DRGs which are then consolidated and, following initial severity and DRG assignments, are further modified by adding a risk adjustment factor and increasing the weight assignment based on the additional severity of the particular case based on additional independent CCs.

APS-DRG Methodology

The right branch of *Figure* 2 illustrates APS-DRG's decision logic by mapping the process by which a final DRG is assigned and includes an additional step to reflect additional adjustments that refine the severity of the APS-DRG based on the number of additional co-morbidities.

Figure 2: Decision Logic



APS -DRGs consolidate DRGs using the same underlying structure of the SDRGs as developed by HCFA, in which all DRGs with and without CCs were consolidated into "CDRGs" as identified in *Figure* 2. In the Medicare modified version of APS-DRGs, DRGs unrelated to the Medicare population were removed. Using this methodology, HSS was able to reduce the number of CMS DRGs (526) to 361 CDRGs, reducing the total number of Medicare modified APS-DRGs to 875 (from 1,154) without compromising the system's ability to appropriately reflect resource consumption or severity. This also leaves enough additional three digit numbers open for new DRGs to be added as new technologies and treatments are developed that require system modifications.

APS-DRGs arrived at 875 total DRGS by splitting CDRGs into three resource-based severity levels: 1) no CCs, 2) with a CC, or 3) with a Major CC. Severity class is obtained by evaluating all independent secondary diagnoses of a patient, taking into account all CCs present, and resulting in a severity class that is detailed, comprehensive, and patient specific.

In addition, the APS-DRG system verifies any CDRG-specific severity class (CC) exclusions that may exist for an individual patient.

Figure 3, below, is based on 3M's assignment of severity chart as provided in the April 26, 2006 NPRM. This figure has been revised to highlight the proposed steps that modified APS-DRG and APR-DRGs (which are the basis of the proposed CSA-DRGs) have in common. Those boxes which are shared are shaded and in italics. The non-shaded boxes apply only to the APR-DRG system, which is the basis for the proposed CSA-DRGs.

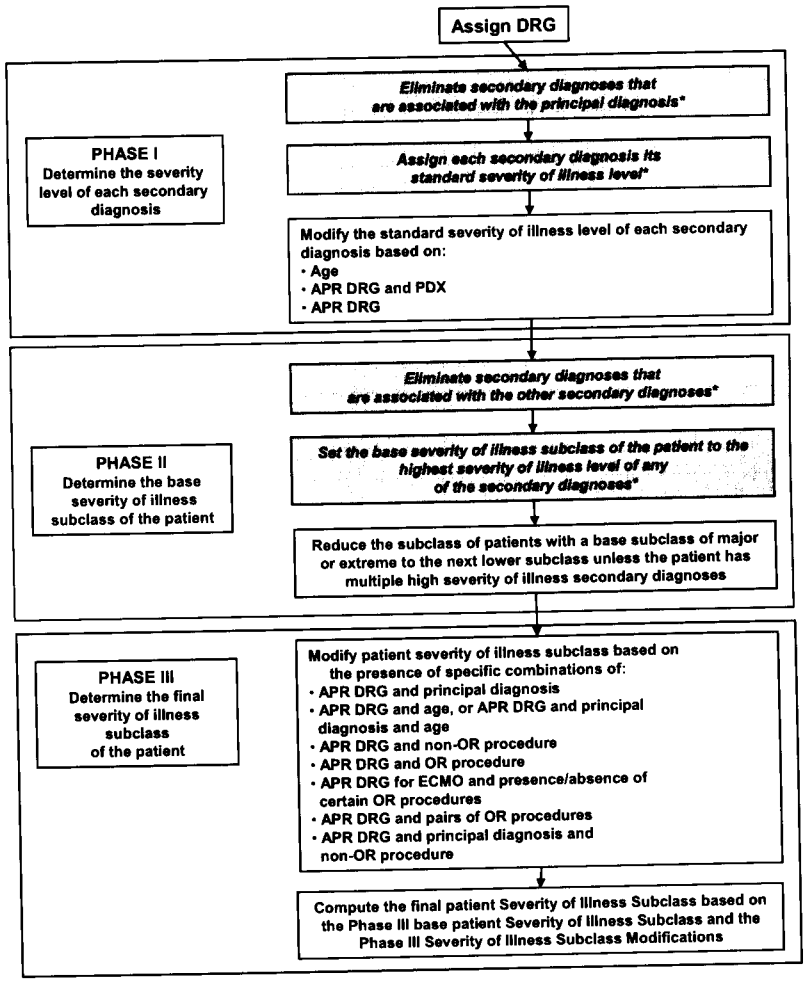
There are 19 steps involved in APS-DRGs assignment of severity (these steps are outlined in the APS-DRG Definitions Manual) prior to the risk and weight adjustments. There is no aggregation of severity classes in this model.

The Proposed Rule in the Federal Register notes that "Section 1886(d)(4) of the Act specifies that the Secretary must adjust the classifications and weighting factors at least annually to reflect changes in treatment patterns, technology, and other factors that may change the relative use of hospital resources. Therefore, we believe a method of recognizing technologies that represent increased complexity, but not necessarily greater severity of illness, should be included in the system."

Since APS-DRGs are derived directly from current CMS DRGs, they also account for complexity of procedures in the same way that current CMS DRGs do. For example, two CMS DRGs exist that differentiate between coronary angioplasty with or without stents, attributing the separate DRG to recognize the difference in complexity with the understanding that the patient may not be more severely ill. Thus, APS-DRGs reflect not only severity of illness, but also capture the complexities that exist and are already recognized through CMS' current DRGs.

The following is an example, provided by Ingenix, of how the APS-DRGs system of add-ons work:

Figure 3: Assignment of DRGs in both the APS-DRG and APR-DRG system



*Shaded boxes in italics indicate shared processes by APS-DRGs and APR-DRGs. Boxes that are unshaded indicate APR-DRG steps only.

A 73-year-old Medicare beneficiary is hospitalized with pneumonia and multiple coexisting clinical conditions as follows:

Diagnosis	Description	Status
486	Pneumonia, Organism NOS	Principal
402.91	Hypertensive Heart Disease with Failure	CC
496	Chronic Airway Obstruction NEC	CC
427.32	Atrial Flutter	CC
428	Congestive Heart Failure NOS	CC

244.9	Hypothyroidism NOS
533.9	Peptic Ulcer NOS
311	Depressive Disorder NEC

The principal diagnosis of 486 (Pneumonia) means that this case will be assigned to MDC 04, Diseases and Disorders of the Respiratory System. The first four secondary diagnoses are all considered CCs under the CMS DRG system as well as under APS-DRGs®. For this reason, the case will group to CMS DRG 089, "Simple Pneumonia and Pleurisy, Age>17, with CC." Under APS-DRGs, the case groups to 0891, which is also "Simple Pneumonia and Pleurisy, Age>17, with CC." Three (3) CCs are not used for assigning the discharge to a casemix category.

Under Medicare Modified APS-DRGs, the example changes in two ways. First, the CDRG is renamed to "Simple Pneumonia and Pleurisy" because pediatric splits have been eliminated. In addition, applying CC exclusion logic to the individual secondary diagnoses eliminates one CC from use in constructing the case-specific weight for this discharge. Specifically, 428.0 ("Congestive Heart Failure NOS") is disqualified from CC status because 402.91 ("Hypertensive Heart Disease with Failure") is also coded on the record. Modified APS-DRGs will assign this case to category 0891 with 2 independent "unused" coexisting clinical conditions with CC status.

Assume that APS-DRG 0891 has a baseline weight of 0.5258 and that each independent CC carries an adjustment factor of .23345 for medical cases in MDC 04. The final weight for this patient is 0.9927, calculated as follows:

A	Baseline Weight	0.5258
B	No. of Ind. CCs	2
C	MDC 04 Medical Adj. Factor	0.23345
A+BxC	Final Weight	0.9927

Development of APS-DRG Casemix Weights

All casemix-based payment systems need to develop a set of weights. In systems using mutually-exclusive cells (e.g., the current CMS DRGs), this process is straightforward. One simply calculates the mean cost for each cell and the mean across all cells. The ratio of the two constitutes a set of weights.

Ingenix decided that its payment for each case would be the sum of a base payment (the payment if no CCs) plus an add-on for each additional minor CC plus another add-on for each additional major CC. Therefore, if a DRG had an add-on payment of X for when a case had one major CC, its add-on payment would be 2X if a case had two major CCs.

As APS-DRGs are a hybrid system, development of its weights entails a two-step process. The first step involves calculating the weights for base payments for each DRG. These are calculated by taking the cases with no CCs and, as above, calculating the mean for each DRG.

The second step involved calculating the add-on percentage for each minor CC and major CC. Working with the cases have at least one CC, Ingenix first calculated the percent deviation as

PD = (actual cost/predicted cost) -1

where the denominator is the mean cost for a DRG as calculated in the first step. In a case-level analysis, this percent deviation is regressed on the number of minor CCs and major CCs as follows:

PD = B1*NCC + B2*NMCC

where NCC is the number of minor CCs, NMCC is the number of major CCs, and the Bs are coefficients to be estimated. (Note, the intercept was suppressed.)

Ingenix chose to run this regression separately for medical and surgical cases for each major diagnostic category (MDC). Given the tradeoff between bias and statistical power, this decision has face validity.

These parameters are used to calculate payment as follows:

W * (1 + B1*NCC + B2*NMCC) * CF

where W is the weight for the relevant DRG and CF is a conversion factor applied to all DRGs. Thus, within this MDC and medical-surgical split, there is an add-on payment of B1 percent for each minor CC and of B2 percent for each major CC.

CSA-DRG Methodology

By contrast, CSA-DRGs incorporate consolidated APR-DRGs with four complexity subclasses: 1) minor or no CC, 2) moderate, 3) major, and 4) extreme. The assignment of a patient to a subclass is a three phase process containing 18 steps. In the first phase, the complexity level of each secondary diagnosis is determined. The second phase determines a base complexity subclass for the patient based on the patient's secondary diagnoses. In the third phase, the final complexity subclass for the patient is determined by incorporating the impact of principal diagnosis, age, non-operating room (non-OR) procedures, and multiple combinations of categories of secondary diagnoses.

Further complicating severity assignment within the APR-DRG system, APR-DRGs also introduced a "re-routing logic" that "reassigns a patient to a new MDC and APR DRG in certain circumstances where the principal diagnosis is overly broad or the sequencing of principal and secondary diagnosis is unclear."[8]

This logic becomes difficult to follow given the complex algorithms used to adjust for severity, and can present difficulties for coders due to its lack of transparency. For example, without the ability to determine which codes are the most crucial to include on a hospital UB-92, hospitals who do not submit claims electronically will have no way of knowing which 9 diagnoses and 6 procedures are the most crucial to include on the forms. This lack of knowledge may result in

[8]Averill, et al. "All Patient Refined Diagnosis Related Groups (APR-DRGs) Methodology Review version 23.0". 3M Health Information Systems. 2006.

decreases in productivity across such hospitals and coders having to devote more time to identifying every possible code and choosing which to use without the decision trees and instructions that have always been available to them during the DRG assignment process.

In addition, unlike APS-DRGs, CSA-DRGs do not account for differences in complexity among different DRGs. The Proposed Rule in the Federal Register states, "If Medicare were to adopt a severity DRG system based on the APR DRG logic but assign cases based on complexity as well as severity as we do under the current Medicare DRG system, such a distinction would represent a departure from the exclusive focus on severity of illness that currently forms the basis of assigning cases in the APR DRG system."

Thus, our evaluation of the APS-DRG and APR-DRG systems indicates that APS-DRG severity assignment process offers several advantages over the complexities of the APR-DRG, and consequently, the CSA-DRG system. Assigning severity levels within the APS-DRG system is a transparent and flexible process that is translatable and able to be replicated by one choosing to understand it. This increases the chances of coders properly following program rules and being efficient in the coding process, as well as potential public acceptance of a severity-based patient classification system.

B. *Comparing Transparency, Costs and Public Availability*

Transparency and the corresponding ability for the public to understand and work with the system selected will be a key part in not only gaining acceptance of the new approach but also limiting implementation and maintenance costs. By continuing to offer a system that is visible and understandable to end users, CMS will be keeping an important tradition of involving the stakeholders in the development and refinement of the system to ensure it is as accurate and fair as possible.

To date, CMS has not provided adequate documentation that includes CC lists and the exclusion logic tables to allow users to fully understand the patient classification and the proposed CSA-DRG assignment process. This may be in part due to the iterative approach taken in refining the system. Some decisions appear to have been made based on different combinations of secondary diagnoses and potential exclusions that make it no longer possible to reconstruct how one might arrive at a specific DRG without using a computerized program. It is our conclusion that the CSA-DRGs are more difficult for potential users to understand than the modified APS-DRGs.

Regardless of which proposal is ultimately selected, CMS will incur some costs in refining the approach both before the issuance of a final rule and throughout implementation and beyond. The less significant the changes are in terms of the overall structure of the classification system, the fewer costs that will be incurred for both the government and provider community. The CSA-DRG system and its apparent multitude of complicated algorithms, although carefully conceived over many years of research and development, make it less transparent, flexible, or amenable to later refinement and modifications. By decreasing the amount of transparency when introducing such new systems, CMS may ultimately increase its implementation and maintenance costs beyond what might be required to implement the modified APS-DRGs.

Given the current budgetary environment, limiting costs of implementing and maintaining any changes in the DRG system, as well as keeping the impact of the changes budget neutral, remain a high priority. The modified APS-DRGs, because they are an extension of the current system with the addition of a risk adjustment feature, will likely limit implementation costs and offer greater administrative ease, as well as the ability to more easily modify and refine the system moving forward.

C. *Ability to Systematically Predict Treatment Costs*

Modified APS-DRGs perform statistically at least as well as CSA-DRGs, and both perform substantively better than the current set of DRGs.

In terms of their ability to explain variance, modified APS-DRGs perform at least as well as CSA-DRGs and, in fact, slightly better. This is true at both the case level and hospital level. (See the table for the regression results and the appendix for a discussion of the underlying methodology used by The Lewin Group in its analysis.)

At the hospital level, the casemix coefficient is higher than 1.0 (and statistically significant) for all three casemix systems. It is 1.36 for the current set of CMS DRGs, 1.20 CSA-DRGs, and 1.07 for the modified APS-DRGs. Because IPPS payment is proportionate to casemix but the regression implies a more-than-proportionate relationship between cost and casemix, high-casemix hospitals are being underpaid relative to low-casemix ones, even after accounting for the add-on payments for teaching and disproportionate share percentage. This problematic pattern would be substantially greater under CSA-DRGs than under modified APS-DRGs.

There are several possible explanations for this pattern of greater-than-proportionate relationship between cost and casemix. First, this hospital-level finding is consistent with "compression," an important issue in all payment systems. The concern here is that the DRG weights are too low for expensive DRGs and too high for inexpensive DRGs, such that the range of payment is "compressed." However, the casemix coefficient is about 1.0 in case-level regressions for all three DRG systems, suggesting that weights themselves are not the problem here.

More plausibly, <u>within</u> a given DRG (or more precisely, within a payment category), high-casemix hospitals have more expensive patients than low-casemix hospitals. This could result from either:

- Heterogeneity of severity within each payment category, with higher mean for high-casemix hospitals; or
- Some other factor that is correlated with having a high casemix. For instance, the payment mechanism has not controlled for all aspects of teaching hospitals.

However, the fact that the greater-than-proportionate pattern is greatly diminished with modified APS-DRGs suggests that its cause is within-payment-category heterogeneity for the current DRGs and CSA-DRGs. Thus, CSA-DRGs would underpay high-casemix hospitals substantially more than APS-DRGs.

In sum, modified APS-DRGs explain at least as much variance as CSA-DRGs and would underpay high-casemix hospitals substantially less.

IV. CONCLUSION

Irrespective of which system CMS eventually chooses to improve its ability to reflect severity, it is incumbent upon CMS to make the grouper logic transparent and publicly available at a minimal cost. This will encourage on-going public discussion and open evaluation of the potential alternatives prior to the final adoption of a severity adjusted DRG system.

After a careful assessment, The Lewin Group has concluded that the modified APS-DRGs are worthy of consideration by CMS and the general public as an alternative to the proposed CSA-DRGs. They offer a simpler, more transparent, and perhaps more accurate approach by essentially extending CMS' approach to DRGs to date and adding the value of the CMS risk adjustment methodologies already used for capitated and psychiatric services to all DRG severity weight assignments. APS-DRGs are statistically sound, offer system stability and flexibility over time, and are both precise and comprehensive.

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Appendix A: Methodology of Regression of Cost on Casemix Measures

For each of the three casemix measures considered here, The Lewin Group regressed cost-per-case on the casemix weight to investigate two questions:

- Would hospitals be paid fairly? That is, would average payment to a hospital (across all its cases) be closely related to its average costs?
- Would payment for each case be closely related to its cost? Here the issue is not fairness per se but rather the potential for "cherry-picking," the potential for a hospital to design policies that would result in a disproportionate percentage of cases that were less expensive to treat than others receiving the payment rate?

To address the hospital-level fairness issue, we performed a hospital-level regression analysis. We examine the "cherry-picking" issue by conducting a case-level regression analysis.

Data

We obtained case-level charge data from 2004 MedPAR (Medicare Provider Analysis and Review) file. From the Medicare Inpatient Impact File, we obtained the cost-to-charge ratios (for operating and capital expenses), CSA-DRG weight, and several variables used to calculate Medicare's payment:

Wage = wage index used under IPPS,
COLA = cost-of-living adjustment (COLA, which equals 1.0 for all states except Alaska and Hawaii),
IRB = payment adjustment factor for teaching hospitals, and
DSH = payment adjustment factor for disproportionate share (DSH) hospitals.

From the Impact File also came:

two cost-to-charge ratios:
Ratio of operating costs to total covered charges and
Ratio of capital costs to total covered charges,

and two outlier variables:
Out_op = operating outlier payments as a percentage of operating IPPS payments and
Out_cap = capital outlier payments as a percentage of capital IPPS payments.

Ingenix/HSS calculated the casemix weight for each case for the current CMS DRG and the modified APS-DRG.

The cost for each case was calculated as the covered charges times the sum of the two charge ratios.

The case-level file was aggregated to the hospital level, with variables for cost per case and weight per case (i.e., casemix index).

Specification

Regressions of cost on casemix typically take one of two forms. In "payment regressions," cost per case is standardized for payment variables (other than casemix) before being regressed on casemix index. In "explanatory regressions," cost per case is regressed on casemix index and other variables related to payment. Both forms of regressions may include variables that are unrelated to payment.

As the conclusions drawn from the two sets of regression are the same, we present only the results for the payment regressions, as they are the simpler of the two.

Cost per case was standardized as follows:

$$\text{Cost} / [(.70*\text{wage} + .30*\text{COLA})\ (1 + \text{IRB} + \text{DSH})].$$

Although outliers affect payment, there is no straight-forward way to use them to standardize cost.

A double-log regression was used, so the log of standardized cost per case was regressed on the log of casemix. The logarithms of each of the two outlier percentage variables (plus one) were also entered in this regression. So the regression was specified as follows:

$$\log(\text{standardized cost per case}) = B0 + B1*\log(\text{casemix index}) + B2*\log(\text{out\_op}+1) + B3*\log(\text{out\_cap}+1)$$

Alternative Casemix Measures as Predictors of Cost-per-Case Standardized by Payment Variables: Hospital and Case Levels

		Hospital Level			Case Level		
		CMS DRGs	CSA-DRGs	APS-DRGs	CMS DRGs	CSA-DRGs	APS-DRGs
Casemix							
	CMS DRGs	1.360			0.981		
		(41.20)			(2927.49)		
	CSA-DRGs		1.203			0.977	
			(44.08)			(3453.17)	
	APS-DRGs			1.072			0.974
				(46.11)			(3551.14)
Outlier % of payment							
	Operating	0.39	0.33	0.52	0.89	0.70	0.73
		(2.68)	(2.35)	(3.78)	(143.24)	(121.82)	(128.29)
	Capital	0.54	0.56	0.50	0.43	0.44	0.44
		(4.54)	(4.83)	(4.33)	(82.50)	(90.05)	(91.98)
Intercept		8.41	8.50	8.55	8.65	8.70	8.71
R-square		0.419	0.446	0.464	0.436	0.517	0.530
F		812.7	906.4	976.4	>1m	>1m	>1m
N		3389	3389	3389	11.6m	11.6m	11.6m

m = million. "CMS DRGs" are the DRGs currently used by CMS. APS-DRGs have been modified for Medicare. T-values are in parentheses. All variables are in logarithmic form.
Source: MedPAC and Impact Files.

United States Senate

COMMITTEE ON FINANCE

WASHINGTON, DC 20510-6200

July 25, 2006

The Honorable Mark McClellan
Administrator
Centers for Medicare and Medicaid Services
200 Independence Avenue, SW
Hubert Humphrey Building
Washington, DC 20201

Dear Dr. McClellan,

We are writing to express concerns regarding the Centers for Medicare and Medicaid Services' (CMS) proposed rule on Revisions to the Payment Policies of Ambulance Services issued on May 26, 2006. We appreciate the efforts that CMS has made to refine payments under the ambulance fee schedule to improve the accuracy of payments for ambulance services as it moves toward full implementation of the national ambulance fee schedule. We have some specific concerns, however, over the proposed adoption of new geographic standards and resulting definitions of urban and rural areas for ambulance fee schedule payment purposes.

CMS has proposed revising the designations for urban and rural areas by replacing the existing Metropolitan Statistical Areas (MSAs) with OMB's new classification system which uses Core-Based Statistical Areas, or CBSAs. The new designations proposed by CMS also take into account changes in the population that have occurred over the 10-year period between 1990 and 2000.

We are concerned about some of the CMS methodology used in the proposal and unintended effects that may occur in the reclassification of rural and urban areas throughout the country with the new CBSA system. CMS has admitted that as many as 40 states could have ambulance providers whose payments will decrease under the new classifications, while only roughly 20 states are expected to have ambulance providers who will receive increased payments. We understand that approximately 32 states will have overall reductions in their ambulance payments as a result of the proposed revisions.

It is difficult to estimate the exact impact of the proposed changes because CMS has proposed implementing these new designations at the same time that they are utilizing new 2000 census data to reflect the population migrations that have occurred throughout the country. In some cases, shifting populations alone could change rural areas to urban ones but without more detailed analysis it is impossible to discern the basis for

determining the new geographic areas since both population shifts and the new CBSA classification system are being factored in simultaneously. It is also not possible to fully comprehend the changes proposed by CMS because they are identified on the basis of zip codes, and we do not have the specific data on affected counties to analyze these changes.

According to CMS, OMB has defined a CBSA in the new system as a "geographic entity associated with at least one core of 10,000 or more population, plus adjacent territory that has a high degree of social and economic integration with the core as measured by commuting ties." The OMB definitions adopted by CMS include two categories of CBSAs – MSAs and Micropolitan Statistical Areas. MSAs are based on "urbanized areas of 50,000 or more population" and are designated as urban. Micropolitan Areas are based on urban clusters of "at least 10,000 population but less than 50,000 population" and are designated as rural. Counties that do not fall within these two CBSAs are considered to be "Outside CBSAs" and are recognized as rural. Areas that meet an updated definition of the Goldsmith Modification designated as Rural-Urban Commuting Area Codes (RUCAs) are also identified as rural tracts within MSAs.

CMS states in their proposal that there are 1,090 counties in MSAs under the new definitions (up from 848 counties previously), and that 288 counties will be considered urban which were formerly rural (not previously designated to any MSA). We have heard concerns expressed that these changed designations will affect some counties which are still entirely rural in nature, with very small populations, but which will now be classified as urban areas under the Agency's proposal. If this is true, counties with very low volume but high percentages of Medicare beneficiaries could lose essential payments such as the rural bonus payments to which they are currently entitled as ambulance providers serving rural areas. Medicare reimbursements under the ambulance fee schedule are already 27% below the national average cost of providing ambulance services to Medicare patients. These payments could decrease by an additional 30 percent or more if the rural bonus payments are lost.

For example, the CMS proposal would change the designation of Washington County, Iowa, from a rural county to a metropolitan one under the new system. Washington County is a farming community of 557 square miles with a population of 20,670, based on the 2000 census. (Based on the 1990 census, the county had a population of 19,612 and was considered entirely rural). The largest city in the county is Washington, with a population of roughly 7,000. The rest of the county is made up of smaller cities such as Kalona (2,300), Wellman (1,400), Riverside (928), Brighton (687) and other small communities. Mileage reimbursement for ambulance providers in Washington County which is currently set at $9.17 would be cut to $6.05, a decrease of 34 percent. The county has a total of roughly 1,150 ambulance transports a year, with Medicare patients accounting for approximately 50 percent of the volume. The proposed mileage payment reductions, which are theoretically based on high-volume urban areas, coupled with ever-rising fuel costs, could spell financial disaster for the limited number of ambulance providers serving low volume, rural areas such as Washington County.

We urge you to reconsider the proposed CBSA changes to the designations of urban and rural areas in light of the impact they could have on many rural areas throughout the country and the ambulance providers who serve these high-cost rural areas and include a more appropriate method of defining rural areas for ambulance reimbursement.

We also request that you provide us with information and maps that would show 1) the impact of the proposed changes, by county, for each state; 2) whether the county's designation has changed, and if so, what change was made; and 3) whether utilizing a different definition of rural for ambulance reimbursement would enable the Agency to more precisely distinguish between urbanized areas and low population density areas and retain rural designations for areas that should be considered rural. CMS has taken steps to more accurately reflect changes in demographics and distinguish between the urban and rural nature of areas. However, more must be done to remedy the proposed designation of truly rural counties as urban counties, such as we have described in the example above.

Thank you for your consideration. If you have any questions, or to follow up with the information we have requested, please contact Sue Walden of Senator Grassley's staff at (202) 224-4515.

Sincerely,

Chuck Grassley

Craig Thomas

Ron Wyden

Trent Lott

Orrin G. Hatch