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The Alliance of Dedicated Cancer Centers:
Arthur G. James Cancer Hospital and Richard J. Solove Research Institute
City of Hope National Medical Center
Dana-Farber Cancer Institute
Fox Chase Cancer Center
H. Lee Moffitt Cancer Center and Research Institute
M.D. Anderson Cancer Center
Memorial Sloan-Kettering Cancer Center
Roswell Park Cancer Institute
Seattle Cancer Care Alliance
Sylvester Comprehensive Cancer Center

November 29, 2005

By Hand

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

Re: File Code CMS-1287-IFC
Medicare Program; Health Care Infrastructure Improvement Program; Selection Criteria of Loan Program for Qualifying Hospitals Engaged in Cancer-Related Health Care; Interim Final Rule with Comment Period

Dear Administrator McClellan:

On behalf of the Alliance of Dedicated Cancer Centers, an alliance of ten nationally recognized institutions focusing exclusively on the care of cancer patients, I am writing to comment on the Interim Final Rule with Comment Period that establishes the criteria for awarding the Health Care Infrastructure Improvement Program loans established by the Medicare Modernization Act of 2003 (MMA), Pub. L. No. 108-173, as published in the *Federal Register* on September 30, 2005 (70 Fed. Reg. 57,368) (the "Interim Final Rule").

As leaders in the war on cancer, the Centers applaud the efforts of Congress in enacting this legislation to address the critical infrastructure needs facing cancer hospitals. Many of the Cancer Centers are involved in, or are planning, extensive capital improvement programs so that they can remain at the forefront of cancer research and treatment. These programs are expensive, however, and loan programs such as that created by the MMA will be critical in ensuring the success of these efforts. The Cancer Centers, individually listed above, appreciate the opportunity to submit these comments.

I. BACKGROUND

As noted in the Interim Final Rule, section 1016 of the MMA established a new loan program designed to help qualifying hospitals pay for the capital costs of eligible projects. This provision defines a "qualifying hospital" as a hospital that is "engaged in research in the causes, prevention, and treatment of cancer; and is designated as a cancer center for the National Cancer Institute or is designated by the State as the official cancer institute of the State." 42 U.S.C. § 1395hhh(c). This definition was subsequently expanded by the Tsunami Relief Act of 2005, Pub. L. No. 109-13, to include tax-exempt entities that have at least one memorandum of understanding with a hospital located in the entity's state and that conduct both cancer research and outpatient cancer care. See id. A separate subsection of the MMA provides for the forgiveness of loans established by the Program if a qualifying hospital establishes cancer outreach, diagnosis, and treatment programs that serve rural areas and Indian tribes, and meets certain other requirements. See 42 U.S.C. § 1395hhh(f).

The Interim Final Rule, however, conflates the provision in the MMA dealing with the definition of a hospital qualifying for a loan with the criteria for forgiveness of such loans. Specifically, the Interim Final Rule creates an evaluation process which prioritizes the approval of a loan under the Program based on whether the recipient would also qualify for loan forgiveness under the criteria articulated in the statute. See 70 Fed. Reg. at 57,370.

II. DISCUSSION

The Centers support the agency's efforts to improve and expand access to cancer treatment to individuals living in underserved rural areas and Indian reservations. We recognize that cancer patients residing in these areas may not otherwise have access to the best available treatments without outreach programs of the type established by the MMA and the Interim Final Rule. However, it is important for the agency to recognize that disparity in access to cancer treatment is a national problem that affects cancer patients throughout the United States, and in urban as well as rural areas. See "Health Care: Approaches to Address Racial and Ethnic Disparities," Government Accountability Office (July 8, 2003). While we understand the current budgetary challenges facing Congress and CMS, we hope the agency will create similar opportunities for those cancer centers that do not qualify for assistance under the narrowly drawn qualifying criteria in the Interim Final Rule.

We are also concerned that, in linking the loan qualification and forgiveness criteria, the agency may be unintentionally misconstruing Congressional intent. As you may be aware, when the Senate originally considered this provision, it included language limiting applicants to cancer centers in states with populations of less than three million. See S. 1, § 2202, 108th Cong. (1st Sess. 2003). However, in the final legislation, this restriction was dropped, indicating that Congress decided not to limit applicants for these loans on the basis of such criteria. By combining the loan qualification and forgiveness criteria, the agency is undermining Congress's decision on this issue. CMS's interpretation is also not a credible reading of the statutory language, which, on its face, uses these two sets of criteria for distinctly different purposes. By reading these two separate and distinct sections of the statute together, the agency is effectively foreclosing many institutions from receiving loans for needed capital improvements, based solely on location and population, rather than on the merits of their applications. We request that CMS

reconsider its position and remove unnecessary limits on entities that can apply for loans under the Program.

III. CONCLUSION

Thank you for your willingness to consider our views. If you have any questions or require additional information, please contact Mr. Anthony Diasio, at (215) 728-3824.

Sincerely yours,

James S. Quirk

James S. Quirk
Senior Vice President
Memorial Sloan-Kettering Cancer Center

University of Colorado at Denver and Health Sciences Center

University of Colorado Cancer Center

Mail Stop 8111
P.O. Box 6511
Aurora, Colorado 80045
Administrative Office: 303-724-3155
Administrative Fax: 303-724-3162
Website: www.uccc.info

November 27, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: Interim Final Rule on the Medicare Program; Health Care Infrastructure Improvement Program; Selection Criteria of Loan Program for Qualifying Hospitals Engaged in Cancer-Related Health Care

Attn: **CMS-1287-IFC**

To Whom It May Concern:

This letter is a formal submission of comment concerning File Code CMS-1278-IFC, relating to the implementation of Section 1016 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) (Pub. L. 108-173). This comment pertains to the rule establishing the criteria for application for project selection, specifically concerning qualifying hospitals located in a State as defined as a "rural State".

Specifically, our comment is directed to *"Section C. Selection Criteria"* found on page 57370 of the **Federal Register** / Vol. 70, No. 189, 42 CFR, Part 505 : *"...we will prioritize qualifying hospitals that meet the following criteria: The hospital is located in a State which based on population density is defined as a rural State. A rural State is one of ten States with the lowest population density"*. A second criterion states, *"The hospital is located in a State with presence of multiple Indian tribes in the State. After prioritizing based on paragraph (b)(1), States are further prioritized based on the States with the most Indian tribes."* In addition there is a clarifying statement at the bottom of middle column found on that same page in the **Federal Register** that states: *"Therefore, we are requiring that qualifying hospitals be located in 1 of the 10 States with the lowest population density in order to receive funding under section 1897 of the Act."*

We are asking for clarification of this interim final rule in that it appears this language specifically excludes loan applications from hospitals located in States not listed on page 57371 of the **Federal Register**. Our concern is that there are many qualifying hospitals located in other States that also provide clinical cancer care outreach services to rural and

Native populations – including to American Indian tribes residing in the ten "Least Densely Populated States" listed.
Accordingly, we offer two recommendations:

1. Amend the proposed interim final rule to delete language that limits applications or funding to only qualifying hospitals located in any one of the ten States identified on page 57371 of the **Federal Register** / Vo. 70, No. 189. Opening the application process to other States would permit hospitals in States that have outreach programs serving rural and more specifically, Native populations to also participate in the loan and loan forgiveness programs.

2. To further assure that loan funds reach as many qualifying hospitals as possible, we suggest you limit the amount of loan funds made available to qualifying hospitals to $10 million per State. This would serve to maximize the greatest benefit to a greater number of applicants.

In suggesting these two changes we feel that the rules would go a long way to address what we understood to be original congressional intent - to maximize the loan funds made available to the broadest number of qualifying hospitals in the greatest number of States. Allowing the rules to stand as written it would preclude already established programs found in States other than those ten listed from applying for loans and loan forgiveness, such as those found at the University of Colorado at Denver and Health Sciences Center and University of Colorado Hospital outreach programs housed at the Ben Nighthorse Campbell Native Health Center.

Thank you for this opportunity to comment on these rules and we are grateful for your consideration of our recommendations.

Sincerely,

Tim Byers, MD, MPH

Tim Byers MD MPH
Deputy Director, University of Colorado Cancer Center

University of Colorado at Denver and Health Sciences Center

University of Colorado Cancer Center

Mail Stop 8111
P.O. Box 6511
Aurora, Colorado 80045
Administrative Office: 303-724-3155
Administrative Fax: 303-724-3162
Website: www.uccc.info

November 23, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: Interim Final Rule on the Medicare Program; Health Care Infrastructure Improvement Program; Selection Criteria of Loan Program for Qualifying Hospitals Engaged in Cancer-Related Health Care

Attn: **CMS-1287-IFC**

To Whom It May Concern:

Please accept this letter as formal submission of comment concerning File Code CMS-1278-IFC, relating to the implementation of Section 1016 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) (Pub. L. 108-173). This comment pertains to the rule establishing the criteria for application for project selection, specifically concerning qualifying hospitals located in a State as defined as a "rural State".

Specifically, our comment is directed to *"Section C. Selection Criteria"* found on page 57370 of the **Federal Register** / Vol. 70, No. 189, 42 CFR, Part 505. It states therein that, "...we will prioritize qualifying hospitals that meet the following criteria: The hospital is located in a State which based on population density is defined as a rural State. A rural State is one of ten States with the lowest population density". A second criteria states, "The hospital is located in a State with presence of multiple Indian tribes in the State. After prioritizing based on paragraph (b)(1), States are further prioritized based on the States with the most Indian tribes." In addition there is a clarifying statement at the bottom of middle column found on that same page in the **Federal Register** that states, "Therefore, we are requiring that qualifying hospitals be located in 1 of the 10 States with the lowest population density in order to receive funding under section 1897 of the Act." We are looking for clarification of this interim final rule in that it appears this language specifically excludes loan applications from hospitals located in States not listed on page

57371 of the **Federal Register**. Our concern is that there are many qualifying hospitals located in other States that also provide clinical cancer care outreach services to rural and Native populations – including to American Indian tribes residing in the ten "Least Densely Populated States" listed.

Accordingly, our first recommendation would be to amend the proposed interim final rule to delete language that limits applications or funding to only qualifying hospitals located in any one of the ten States identified on page 57371 of the **Federal Register** / Vo. 70, No. 189. By opening the application process to additional States it would permit hospitals in those States that have outreach programs serving rural and more specifically, Native populations to also participate in the loan and loan forgiveness programs.

To further assure that loan funds reach as many qualifying hospitals as possible, our second proposed rule change would be to limit the amount of loan funds made available to qualifying hospitals to $10 million per State. This would serve to maximize the greatest benefit to a greater number of applicants.

In suggesting these two changes we feel that the rules would go a long way to address what we understood to be original congressional intent – to maximize the loan funds made available to the broadest number of qualifying hospitals in the greatest number of States. Our suggested changes could also assure that qualifying facilities in other States with well established programs of cancer research and outreach to rural and Native populations would have the opportunity to ultimately benefit from this loan program.

If the proposed interim rules stand as written it would preclude already established programs found in States other than those ten listed from applying for loans and loan forgiveness, such as those found at the University of Colorado at Denver and Health Sciences Center and University of Colorado Hospital outreach programs housed at the Ben Nighthorse Campbell Native Health Center.

With regard to the proposed rule pertaining to application for loan forgiveness, (file code CMS-1320-P), we endorse this rule as proposed noting the positive criteria for loan forgiveness strongly emphasizing research and service to rural and Native populations.

Thank you for this opportunity to comment on these rules and we are grateful for your favorable consideration of our recommendations.

Sincerely,

Paul A Bunn Jr. MD

Paul A. Bunn, Jr., MD
Director, University of Colorado Cancer Center

UNIVERSITY OF COLORADO HOSPITAL

November 23, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: Interim Final Rule on the Medicare Program; Health Care Infrastructure Improvement Program; Selection Criteria of Loan Program for Qualifying Hospitals Engaged in Cancer-Related Health Care

Attn: **CMS-1287-IFC**

To Whom It May Concern:

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OFFICE OF THE PRESIDENT

13001 East 17th Place • Building 500 • Room C1015
P.O. Box 6508 • Mail Stop F417 • Aurora, Colorado 80045-0508 • Phone 303.724.5773 • Fax 303.724.5838
University of Colorado at Denver and Health Sciences Center

Accordingly, our first recommendation would be to amend the proposed interim final rule to delete language that limits applications or funding to only qualifying hospitals located in any one of the ten States identified on page 57371 of the **Federal Register** / Vo. 70, No. 189. By opening the application process to additional States it would permit hospitals in those States that have outreach programs serving rural and more specifically, Native populations to also participate in the loan and loan forgiveness programs.

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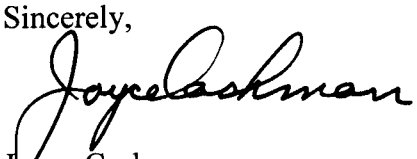
In suggesting these two changes we feel that the rules would go a long way to address what we understood to be original congressional intent – to maximize the loan funds made available to the broadest number of qualifying hospitals in the greatest number of States. Our suggested changes could also assure that qualifying facilities in other States with well established programs of cancer research and outreach to rural and Native populations would have the opportunity to ultimately benefit from this loan program.

If the proposed interim rule stands as written it would preclude already established programs found in States other than those ten listed from applying for loans and loan forgiveness, such as those found at the University of Colorado at Denver and Health Sciences Center and University of Colorado Hospital outreach programs housed at the Ben Nighthorse Campbell Native Health Center.

With regard to the proposed rule pertaining to application for loan forgiveness, (file code CMS-1320-P), we endorse this rule as proposed noting the positive criteria for loan forgiveness strongly emphasizing research and service to rural and Native populations.

Thank you for this opportunity to comment on these rules and we are grateful for your favorable consideration of our recommendations.

Sincerely,



Joyce Cashman,
Interim President and CEO

JC:ceg

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THE OHIO STATE UNIVERSITY
JAMES CANCER HOSPITAL AND SOLOVE RESEARCH INSTITUTE

UniversityHospitals HealthSystem

University Hospitals of Cleveland

November 22, 2005

Administrator Mark McClellan, M.D.
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: CMS 1287-IFC

Dear Administrator McClellan:

The Ohio State University – Arthur G. James Cancer Hospital and Richard J. Solove Research Institute and University Hospitals of Cleveland – Ireland Cancer Center, both not-for-profit academic health centers and two of the nation's leading cancer centers, appreciate the opportunity to comment on this interim Final Rule. The Interim Final Rule with Comment Period that establishes the criteria for awarding the Health Care Infrastructure Improvement Program loans created by the Medicare Modernization Act of 2003 (MMA), Pub. L. No. 108-173, as published in the *Federal Register* on September 30, 2005 (70 Fed. Reg. 57,368) (the "Interim Final Rule").

As noted in the Interim Final Rule, Section 1016 of the MMA established a new loan program designed to help qualifying hospitals pay for the capital costs of eligible projects. This provision defines a "qualifying hospital" as a hospital that is "engaged in research in the causes, prevention, and treatment of cancer; and is designated as a cancer center by the National Cancer Institute or is designated by the State as the official cancer institute of the State." 42 U.S.C. § 1395hhh(c). This definition was subsequently expanded by the Tsunami Relief Act of 2005, Pub. L. No. 109-13, to include tax-exempt entities that have at least one memorandum of understanding with a hospital located in the entity's state and that conduct both cancer research and outpatient cancer care. See id.

A separate subsection of the MMA provides for the forgiveness of loans established by the Program if a qualifying hospital establishes cancer outreach, diagnosis, and treatment programs that serve rural areas and Indian tribes, and meets certain other requirements. See 42 U.S.C. § 1395hhh(f). The Interim Final Rule creates an evaluation process which prioritizes the approval of a loan under the Program based on whether the recipient would also qualify for loan forgiveness under the criteria articulated in the statute. See 70 Fed. Reg. at 57,370.

We have examined the above section (now Section 1879 of the Social Security Act) and believe the Agency has misread this provision in its promulgation of eligibility criteria that limit its application to cancer centers in certain rural areas. While there was considerable emphasis on rural designations in the original House and Senate provisions, these were eliminated in the conference report and legislative language that became Section 1016 in the MMA. We believe that this broadening of language illustrates congressional intent to widen eligibility rather than to severely restrict it. There is no language in the conference report or law that references Section 410A of the MMA as a guiding principle for Section 1016. Further, this provision of the MMA is not even located in the section of the Act devoted to rural matters.

As leaders in the war on cancer, we applaud the efforts of Congress in enacting this legislation to address the critical infrastructure needs facing cancer hospitals. Many of the Cancer Centers are involved in, or are planning, extensive capital improvement programs so that they can remain at the forefront of cancer research and treatment. These programs are expensive, and loan programs such as that created by the MMA will be critical in ensuring the success of these efforts.

We request that CMS reconsider its position and remove unnecessary limits on entities that can apply for loans under the Program. Thank you for your willingness to consider our views. If you have any questions or require additional information, please contact Jennifer K. Carlson, Director of Government Relations, OSU's Comprehensive Cancer Center - Arthur G. James Cancer Hospital And Richard J. Solove Research Institute, at 614-293-0346 or Heidi L. Gartland, Vice President of Government Relations, Ireland Cancer Center at 216-844-3985.

Sincerely,

David E. Schuller, M.D.
Senior Executive Director, Arthur G. James Cancer Hospital and Richard J. Solove Research Institute
Deputy Director, Comprehensive Cancer Center
John W. Wolfe Chair in Cancer Research

Fred C. Rothstein M.D.
President & CEO
University Hospitals of Cleveland

Michael A. Caligiuri, M.D.
Director, Comprehensive Cancer Center
Deputy Director, Arthur G. James Cancer Hospital and Richard J. Solove Research Institute
John L. Marakas Nationwide Insurance Enterprise Foundation Chair in Cancer Research

Stanton L. Gerson, M.D.
Director
Case Comprehensive Cancer
Ireland Cancer Center Center
University Hospitals of Cleveland

Cc: Congressman Ralph Regula
Congresswoman Deborah Pryce
Congresswoman Stephanie Tubbs Jones
Congressman Dave Hobson
Congressman Pat Tiberi
Senator Mike DeWine
Senator George Voinovich