

Comment 3: One comment suggested that part (b) of the SBA's definition of a small business concern, specifying an entity "which has not assigned, granted, conveyed or licensed * * * any rights in the invention" to a large entity should be deleted from the definition as being inappropriate. The comment stated that a license or other agreement between a small entity and a large entity does not typically result in substantial income to the small entity. The comment further asserted that in most cases the small entity retains the financial responsibility to pay the patent prosecution and maintenance fees, without any additional income from the large entity. The comment contended that if the license or other agreement is later terminated, the termination agreement often allows the large entity to retain some rights without further payment. Additionally, the termination agreement may be so complex that the small entity may not be able to overcome a charge of inequitable conduct by a third party. Alternatively, one of the comments stated that the adopted size standard does not unfairly burden small entities because a large entity typically pays the cost of patent prosecution when a small entity licenses its technology to the large entity.

Response: 13 CFR 121.802 is the substantive provision for determining whether an entity is a small business concern for purposes of paying reduced patent fees. The USPTO did not propose to change the definition of a small business concern for the purpose of paying reduced patent fees. Rather, the USPTO was inviting public comment on the establishment of the SBA business size standard in 13 CFR 121.802 as the size standard when conducting an analysis or making a certification under the Regulatory Flexibility Act for patent-related regulations.

Moreover, the suggestion was previously considered and rejected in the rule making to implement the reduction in patent fees for small entities. Specifically, a past comment suggested that 37 CFR 1.27 should be corrected to indicate that a small business concern would be entitled to pay reduced patent fees even though the small business concern may grant a non-exclusive or an exclusive license to a non-small entity. The USPTO responded as follows:

Section 1.27 requires that the concern qualify as a small business concern as defined in § 1.9(d). Section 1.9(d) defines a small business concern by incorporating 13 CFR 121.3-18, which in turn defines a small business concern as one not exceeding a particular size "which has not assigned,

granted, conveyed, or licensed, and is under no obligation under contract or law to assign, grant, convey or license, any rights in the invention to any person who could not be classified as an independent inventor if that person had made the invention, or to any concern which would not qualify as a small business concern or a nonprofit organization under this section." The intent of both 13 CFR 121.3-18 and 37 CFR 1.9(d) and 1.27(c) is to limit the payment of reduced fees under section 41(a) and (b) of Title 35, United States Code, to those situations in which all of the rights in the invention are owned by small entities, i.e., independent inventors, small business concerns, or nonprofit organizations. To do otherwise would be clearly contrary to the intended purpose of the legislation which contains no indication that fees are to be reduced in circumstances where rights are owned by non-small entities. Adopting the suggestion might, for example, permit a non-small entity to transfer patent rights to a small business concern which would pay the reduced fees and grant an exclusive license to the non-small entity.

Revision of Patent and Trademark Fees, 47 FR 43273 (Sept. 30, 1982) (final rule). Therefore, the suggested change is not adopted.

Comment 4: One comment noted an error in the following text: "The SBA Advocacy, however, has questioned whether the USPTO's size standard is under-inclusive because it excludes any business concern that has assigned, granted, conveyed, or licensed (and is under no obligation to do so)." The comment suggested the following correction: "The SBA Advocacy, however, has questioned whether the USPTO's size standard is under-inclusive because it excludes any business concern that has assigned, granted, conveyed, or licensed (or is under an obligation to do so)."

Response: The USPTO notes that the text at issue should have read: "The SBA Advocacy, however, has questioned whether the USPTO's size standard is under-inclusive because it excludes any business concern that has assigned, granted, conveyed, or licensed (or is under an obligation to do so) any rights in the invention to any person who made it and could not be classified as an independent inventor, or to any concern which would not qualify as a non-profit organization or a small business concern under [13 CFR 1.802]."

Establishment of a Definition of "Small Business Concern" for Purposes of the USPTO Conducting an Analysis or Making a Certification under the Regulatory Flexibility Act for Patent-Related Regulations: The Regulatory Flexibility Act permits an agency head to establish, for purposes of Regulatory Flexibility Act analysis and certification, one or more definitions of

"small business concern" that are appropriate to the activities of the agency, after consultation with the Office of Advocacy of the Small Business Administration and opportunity for public comment. See 5 U.S.C. 601(3) and 13 CFR 121.903(c). The USPTO consulted with SBA Advocacy and published a request for comments on the establishment of a business size standard (the SBA business size standard set forth in 13 CFR 121.802 for the purpose of paying reduced patent fees) for USPTO Regulatory Flexibility Analysis for patent-related regulations. See *Size Standard for Purposes of United States Patent and Trademark Office Regulatory Flexibility Analysis for Patent-Related Regulations*, 71 FR at 38388-89, 1309 Off. Gaz. Pat. Office at 37-38. Therefore, the USPTO is establishing the following definition of small business concern for purposes of the USPTO conducting an analysis or making a certification under the Regulatory Flexibility Act for patent-related regulations: A small business concern for Regulatory Flexibility Act purposes for patent-related regulations is a business or other concern that: (1) Meets the SBA's definition of a "business concern or concern" set forth in 13 CFR 121.105; and (2) meets the size standards set forth in 13 CFR 121.802 for the purpose of paying reduced patent fees, namely, an entity: (a) Whose number of employees, including affiliates, does not exceed 500 persons; and (b) which has not assigned, granted, conveyed, or licensed (and is under no obligation to do so) any rights in the invention to any person who made it and could not be classified as an independent inventor, or to any concern which would not qualify as a non-profit organization or a small business concern under this definition.

Dated: November 9, 2006.

Jon W. Dudas,

Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.

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DEPARTMENT OF DEFENSE

Office of the Secretary

Office of the Secretary of Defense (Health Affairs)/TRICARE Management Activity

AGENCY: Department of Defense.

ACTION: Notice of a TRICARE demonstration project for the State of Alaska

SUMMARY: This notice is to advise interested parties of a Military Health System (MHS) demonstration project entitled TRICARE Provider Reimbursement Demonstration Project for the State of Alaska. The delivery of health care services in the State of Alaska represents a unique situation that cannot be addressed fully by strictly applying the same reimbursement rules that apply to TRICARE programs in the other 49 states without some modification. Typically, provider payments are the same as under Medicare, unless the Department has taken specific action to increase payment rates in response to a particular, severe access problem in a location. Under this demonstration, payment rates for physicians and other non-institutional individual professional providers in the State of Alaska will be set at a rate higher than the Medicare rate. The demonstration project will test the effect of this change on provider participation in TRICARE, beneficiary access to care, cost of health care services, military medical readiness, morale and welfare. In particular, the demonstration will test whether the increased costs of provider payments are offset in whole or part by savings in travel costs, lost duty time, and other factors. This demonstration will be conducted under statutory authority provided in 10 U.S.C. 1092.

EFFECTIVE DATE: January 1, 2007. This demonstration will remain in effect for a period of 3 years.

ADDRESSES: TRICARE Management Activity (TMA), TRICARE Operations Directorate, 5111 Leesburg Pike, Suite 810, Falls Church, VA 22041-3206.

FOR FURTHER INFORMATION CONTACT: CAPT Cynthia DiLorenzo, Office of the Assistant Secretary of Defense (Health Affairs)—TRICARE Management Activity, telephone (619) 236-5304.

SUPPLEMENTARY INFORMATION:

A. Background

Alaska is a land of extremes and contradictions. It is the largest state in the United States, containing one-fifth of all United States land, yet is one of the least populated. It boasts both the highest mountain in North America and the longest coastline of any state. There are just a few major roads providing residents the ability to travel to the major cities in the State. Other means of transportation are by boat or plane, which places severe hardships on beneficiaries attempting to access needed health care services. It has geography characterized by harsh ice islands and desert tundra. Alaska's citizens are no less diverse.

Alaska's population is just under 627,000. Of these, approximately 71,000 are Military Health System (MHS) beneficiaries. More than half of these beneficiaries reside in south-central Alaska in the State's largest city—Anchorage. Alaska's military treatment facilities (MTFs) meet a large percentage of Alaska's beneficiary health care needs. Those remaining are referred to local civilian providers or to the lower 48 states. Access to health care services in Alaska is often severely limited by the overall dearth of providers, their reluctance to accept TRICARE payment rates, transportation issues, and other factors. In response TRICARE has taken steps to increase payment rates, as detailed below.

B. Past Efforts to Address Access Issues

In 2000, TRICARE created a new payment locality encompassing all of Alaska except Anchorage, and increased payment rates by 28 percent in the new locality. In 2004, pursuant to specific Congressional action, Medicare increased its payment rates in Alaska by 50 percent, and TRICARE rates were increased to match the new Medicare rates. The higher Medicare rates continued through the end of 2005, when the special Congressional provision expired; the Medicare rates reverted to former levels. TRICARE rates reverted to their former level, 28 percent higher than Medicare rates.

C. Other Payers in Alaska

As noted, TRICARE payment rates in Alaska are 28 percent above Medicare rates. It is estimated that commercial rates in Alaska are about 70 percent above TRICARE rates. The Department of Veterans' Affairs purchases some health care services for Veterans in Alaska, using a specially developed rate schedule. Most rates are higher than TRICARE rates, and a few are lower; on average, the VA rates are approximately 35 percent higher than TRICARE rates.

D. Current Status of Access

Large numbers of providers in Alaska are considering no longer treating military beneficiaries owing to low payment rates. Over 70 providers or provider groups in a wide range of specialties are of concern, some of them the sole provider in Alaska for their specialty.

The alternatives to local purchase of services for military officials are to transport patients to Seattle or another location for treatment, or to relocate scarce military medical assets to Alaska to provide services. The first is an expensive proposition that brings with it considerable lost duty time and other

complications; the second approach is untenable in wartime, and as a practical matter medical practice in Alaska would not provide sufficient opportunity for military medical specialists to maintain their skills.

Under a recent policy change, TRICARE limits its payment in cases where Medicare providers "opt out" of Medicare and enter into private contracts with Medicare patients. This may be problematic in Alaska, with the very small number of providers available.

E. Description of Demonstration Project

Under this demonstration, DoD will waive, for services provided in the State of Alaska, the provisions of 10 U.S.C. section 1079(h) that require TRICARE payments for physicians and other individual professional, non-institutional providers to be the same as under Medicare. Instead, TRICARE will adopt a rate that is 1.35 times the current TRICARE allowable rate. In addition, DoD will be the primary payer for services obtained from providers who have opted out of Medicare by Medicare-eligible uniformed services beneficiaries.

This action will directly increase reimbursement levels for providers, and is expected to result in increased access to care for military beneficiaries; reduced travel to Seattle, accompanied by a reduction in lost duty days; and improved morale for military members and families as a result of increased access and reduced separation.

F. Implementation

The demonstration will go into effect on January 1, 2007.

G. Evaluation

An independent evaluation of the demonstration will be conducted. The evaluation will be designed to use a combination of administrative and survey measures of health care access to provide analyses and comment on the effectiveness of the demonstration in meeting its goal of improving beneficiary access to health care by maximizing the potential pool of health care providers in Alaska.

Dated: November 14, 2006.

L. M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

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