

The patent rights in these inventions have been assigned and/or exclusively licensed to the government of the United States of America.

The prospective exclusive license territory may be worldwide and the field of use may be limited to the use of Licensed Patent Rights for the following: "Treating GNE Myopathy (also referred to as distal myopathy with rimmed vacuoles (DMRV), Nonaka myopathy, muscular dystrophy hereditary inclusion body myopathy (HIBM) or inclusion body myopathy type 2 (IBM2)) and kidney disorders due to hyposialylation of the glomerulae or sialic acid deficiency including but not limited to minimal change disease glomerulopathy, focal segmental glomerulosclerosis and membranous nephropathy, in humans with oral formulations of N-acetyl mannosamine (ManNAc) or derivative."

N-Acetyl Mannosamine is a precursor for the synthesis of sugar molecules known as sialic acids which play an important role in specific biological processes such as cellular adhesion, cellular communication and signal transduction. Lack of sialic acids also play an important role in disease processes such as cancer, inflammation and immunity.

This invention relates to methods of administering ManNAc or its derivative (to produce sialic acid in patients who are deficient in the sugar molecule) to treat GNE Myopathy (also referred to as distal myopathy with rimmed vacuoles (DMRV), Nonaka myopathy, muscular dystrophy hereditary inclusion body myopathy (HIBM) or inclusion body myopathy type 2 (IBM2)), and kidney disorders due to hyposialylation of the glomerulae or sialic acid deficiency may be treated by this method as well.

This notice is made in accordance with 35 U.S.C. 209 and 37 CFR part 404. The prospective exclusive license will be royalty bearing, and the prospective exclusive license may be granted unless within fifteen (15) days from the date of this published notice, the National Human Genome Research Institute receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR part 404.

In response to this Notice, the public may file comments or objections. Comments and objections, other than those in the form of a license application, will not be treated confidentially, and may be made publicly available.

License applications submitted in response to this Notice will be presumed to contain business

confidential information and any release of information in these license applications will be made only as required and upon a request under the Freedom of Information Act, 5 U.S.C. 552.

Dated: November 30, 2017.

Claire T. Driscoll,

Director, NHGRI Technology Transfer Office.

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DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Revenue Modernization: Mobile Collections & Receipt (MCR) Pilot

AGENCY: U.S. Customs and Border Protection; DHS.

ACTION: General notice.

SUMMARY: This document announces that U.S. Customs and Border Protection (CBP) will be conducting a pilot test program to allow for the electronic payment of certain taxes and fees imposed on commercial vessels prior to or upon a vessel's arrival at four designated ports of entry. The pilot also introduces portable, electronic devices that authorized CBP employees will use to electronically process payments of certain taxes and fees and to send electronic receipts via email. The pilot will not affect the amount of taxes and fees due, the clearance process, or the proof of documentation required to be presented to CBP. This notice describes the pilot, including its purpose, procedures, locations, and how to participate, and invites public comment on any aspect of the pilot.

DATES: The pilot will begin no earlier than January 8, 2018 and will continue for 18 months at the designated ports of entry. Comments concerning this notice and all aspects of the pilot may be submitted at any time during the pilot to the address set forth below.

ADDRESSES: Written comments concerning any aspect of the pilot should be submitted to the CBP Revenue Modernization ("Rev Mod") Office at revmod@cbp.dhs.gov. In the subject line of your email please indicate "Comment on Mobile Collections & Receipt Pilot."

FOR FURTHER INFORMATION CONTACT:

Kathleen Druit, Rev Mod Program Manager, Office of Finance, U.S. Customs and Border Protection, via email at kathleen.c.druit@cbp.dhs.gov or by telephone at (202) 427-8448. For

additional information, please visit www.cbp.gov/368.

SUPPLEMENTARY INFORMATION:

Background

U.S. Customs and Border Protection (CBP) collects various maritime taxes and fees with regard to commercial vessels that enter ports of entry, proceed coast-wise, or utilize certain customs services at a port. These maritime taxes and fees include tonnage taxes and light money, Consolidated Omnibus Budget Reconciliation Act (COBRA) user fees, Agriculture Quarantine and Inspection (AQI) user fees, and navigation fees.¹ CBP regulations require payment of these taxes and fees by cash or check and specify a paper-based payment process that occurs at the ports.

Current Payment Methods

CBP regulations require that most customs duties, taxes, fees, interest, and other charges be paid by cash or check. See title 19 Code of Federal Regulations section 24.1 (19 CFR 24.1). Accordingly, a party responsible for the payment of commercial vessel maritime taxes and fees must pay all applicable tonnage taxes, light money, COBRA user fees, AQI user fees, and navigation fees, including the prepayment of annual COBRA user fees, by cash or check only. Maritime taxes and fees cannot be paid by credit card or through any other electronic method.

Current Payment Process

Pursuant to CBP regulations, maritime taxes and fees are paid at the port to an authorized CBP employee either onboard the vessel or at the port office. See 19 CFR 24.2. Specifically, all applicable tonnage taxes, light money, and COBRA user fees must be paid to an authorized CBP employee on arrival at a port of entry. See 19 CFR 4.20 (tonnage taxes and light money) and 19 CFR 24.22(b) (COBRA user fee). Annual COBRA user fees may be prepaid. In such case, they must be paid at the port office. See 19 CFR 24.22(b)(3). Navigation fees and AQI user fees must be paid at the time the applicable service is provided. See 19 CFR 4.98 (navigation fees) and 7 CFR 354.3(b) (AQI user fee).

When a cash register is unavailable to process a payment, such as when

¹ See 46 U.S.C. 60301-60303 and 19 CFR 4.20-4.23 (tonnage tax and light money); 19 U.S.C. 58c and 19 CFR 24.22(b) (COBRA user fees); 19 U.S.C. 58a and 19 CFR 4.98 (navigation fees); and 21 U.S.C. 136a and 7 CFR 354.3(b) (AQI user fees). CBP collects AQI user fees pursuant to an inter-agency agreement with the U.S. Department of Agriculture's Animal and Plant Health Inspection Service.

payment is made directly to a CBP officer, the officer must process the payment by filling out CBP Collection Receipt Form 368 (Form 368) and, if tonnage tax is paid, a Certificate of Payment of Tonnage Tax Form 1002 (Form 1002). See 19 CFR 4.23. Form 368 is used to process payments of maritime taxes and fees. It is a serially-numbered, triplicate carbon-copy form that comes in books of 50. Form 1002 is used by CBP to confirm a vessel owner's payment of tonnage tax. It is a serially-numbered, carbon-copy duplicate form. Both forms are used by vessel owners to provide evidence to CBP officers at other ports or at subsequent entries that a particular tax or fee has been paid.

In order to process a payment using Form 368 or 1002, the CBP officer must manually calculate the applicable taxes and fees due, manually complete the forms, and collect the cash or check payment. CBP employees must then process the payment by manually entering the payment information into CBP systems. CBP must treat the Form 368 books as cash and must perform multiple processes to ensure their security and accuracy, including taking inventory, auditing completed books, auditing in-use books, accounting for lost books, and investigating any alleged misuse of books. Additionally, a CBP officer who collects payment for an amount over \$100 in the form of a government check, personal check, traveler's check, or money order must obtain the approval and signature of the Customs officer in charge in order to accept the payment. See 19 CFR 24.1(b)(2). Upon payment, the CBP officer provides the commercial vessel operator with a carbon copy of the completed Form 368 and Form 1002, if applicable, which the vessel operator may use as proof of payment at subsequent ports and entries.

Revenue Modernization: Mobile Collections & Receipt Pilot

The Mobile Collections & Receipt (MCR) pilot introduces the MCR system, which through its interface with *Pay.gov*² and the Automated Commercial Environment (ACE), will enable entities that are participating in the pilot to pay certain commercial vessel taxes and fees online upon or prior to the vessel's arrival at designated ports of entry. The commercial vessel maritime taxes and fees eligible for payment online through this pilot are:

regular tonnage tax, special tonnage tax, light money, COBRA user fees, including the prepayment of the annual COBRA fee, AQI user fees, and navigation fees. Additionally, pursuant to the pilot, CBP will use the MCR system to electronically process payments of commercial vessel taxes and fees made at the port and to send electronic versions of Forms 368 and 1002 via email.

Purpose of the Pilot

CBP is working towards the elimination of cash and check payments of maritime taxes and fees by allowing for electronic payments and automating the collection and receipt process. The purpose of the MCR pilot is to modernize the payment and processing of commercial vessel maritime taxes and fees for pilot participants by introducing a new optional electronic payment method, automating the calculation of fees, and introducing electronic receipts.

The pilot will provide benefits to both CBP and to commercial vessel owners and operators. Cash and check collection at the port of entry is a manual, burdensome, and time-consuming process. The automation and online payment option for certain taxes and fees will reduce the time necessary to accept and process a payment, improve processing and clearance times of vessels, and ensure applicable fees are calculated correctly. This will result in cost savings for pilot participants.

Additionally, the pilot will enable CBP to process the collection, accounting, and transmittal of maritime taxes and fees more efficiently. Under the pilot, CBP officers will no longer be required to manually calculate applicable fees, manually complete Forms 368 and 1002, perform the various manual audit and security processes related to the protection of Form 368 books, or manually enter data when payments are made by cash or check. Under the pilot, CBP officers will not be required to obtain the signature of the Customs officer in charge for payments over \$100 made with a government check, personal check, traveler's check, or money order. These increased efficiencies will provide CBP officers more time to perform higher priority mission support activities.

Participation in the Pilot

Any commercial vessel agent or other entity responsible for payment of commercial vessel taxes and fees at designated ports of entry may participate in the pilot. At this time, only four ports of entry, discussed below, are designated. No application is

required to participate. However, in order to receive notification emails from the MCR system, a commercial vessel agent or other party submitting payment must create an MCR profile and maintain a valid email address as part of the profile. For more information and for instructions on how to create an MCR profile, visit www.cbp.gov/368. When a commercial vessel arrives at a designated port, the vessel's agent or other party wishing to receive email notifications or receive electronic versions of Forms 368 and 1002 will be able to confirm his or her email address and provide additional email addresses for this purpose.

Description and Implementation of the Pilot

The MCR pilot authorizes entities that are participating in the pilot to pay certain commercial vessel taxes and fees online through the MCR Web site with respect to vessels arriving at designated ports of entry. Additionally, CBP employees will be able to access the MCR system through either a portable, electronic device or a desktop computer to view commercial vessel arrival data, automatically calculate applicable fees, electronically process payments, create electronic versions of Forms 368 and 1002, and send the forms via email.

Online Payments

The MCR system will automatically identify the commercial vessels that are due to arrive within a certain number of days at the designated ports of entry. The MCR system will then determine whether the arrival information submitted to CBP through approved electronic data interchange systems, such as ACE, is sufficient to calculate the applicable maritime taxes and fees due for each commercial vessel. If there is sufficient information, CBP will send a notification email to those carriers or vessel agents that have created a profile with the MCR system. The notification email will state that the applicable maritime taxes and fees have been calculated for a specific commercial vessel and payment can now be made on the MCR Web site. The party responsible for payment will then have the opportunity to log-on to the MCR Web site, review the calculated amount of taxes and fees due, and, through MCR's interface with *Pay.gov*, submit payment online through *Pay.gov*. After payment is accepted, the MCR system will send an electronic version of Form 368 and Form 1002, if applicable, to the email address or addresses provided by the party that made the payment. Electronic payments will be accepted on the MCR Web site from prior to the

² *Pay.gov* is a Web site managed by the Department of Treasury that enables individuals to make online payments to the federal government using various forms of payment, including credit cards, debit cards, direct debit, or digital wallet services such as PayPal.

vessel's arrival and up to the time the vessel is cleared by CBP. Payments required for CBP clearance must be made before clearance is granted.

Only commercial vessel maritime taxes and fees are eligible for prepayment online through this pilot. The commercial vessel maritime taxes and fees eligible for potential prepayment online through this pilot are: Regular tonnage tax, special tonnage tax, light money, COBRA user fees, including the prepayment of the annual COBRA fee, AQI user fees, and navigation fees. CBP may expand the pilot to include additional taxes and fees. Any expansion of the fees that are eligible for online payment will be announced in the **Federal Register** and posted on the CBP Web site, <http://www.cbp.gov>.

Process at the Designated Ports of Entry

When a commercial vessel arrives at a designated port of entry, a CBP employee will access the MCR system to determine whether the applicable taxes and fees have been prepaid online for that vessel. If the applicable taxes and fees have not been prepaid online, the vessel agent or other party responsible for payment will have the option to pay all applicable taxes and fees either electronically through the MCR system or at the port of entry with cash or check. If payment is made by cash or check, the CBP officer accepting payment will access the MCR system to review any relevant arrival information, automatically calculate the applicable fees, prepare an electronic version of Form 368 and Form 1002, if applicable, and email an electronic copy of the forms to the vessel operator, owner, or agent. In all situations, CBP officers will have the ability to review, amend, or add data as needed to accurately calculate applicable taxes and fees prior to entering or clearing a vessel.

Throughout the pilot, commercial vessel agents and other entities responsible for payment will continue to be able to pay applicable maritime taxes and fees to an authorized CBP employee by cash or check. CBP will provide electronic versions of Forms 368 and 1002 as a receipt for all payments, regardless of whether payment was made in person by cash or check or paid online. The port office will provide paper copies of Forms 368 and 1002 upon request.

This pilot will not affect the amount of taxes and fees due or the requirement that all applicable fees must be paid prior to the issuance of a clearance certificate. Additionally, vessel operators will continue to be required to present paper copies of Forms 368 and

1002 as proof of payment at subsequent ports and entries.

Designated Ports of Entry and Duration of the Pilot

The pilot will initially operate at the following ports of entry: Los Angeles-Long Beach, California; New Orleans, Louisiana; Gulfport, Mississippi; and, Mobile, Alabama.

The pilot will begin no earlier than January 8, 2018 and will continue for 18 months. If it is determined that the pilot is working successfully at these initial ports, the pilot may be expanded to additional ports of entry, extended for an additional period of time, and/or expanded to include additional maritime fees, taking into consideration any comments that are received. Any expansion or extension of the pilot would be announced in the **Federal Register**.

Privacy

CBP will ensure that all Privacy Act requirements and applicable policies are adhered to during the implementation of this pilot.

Paperwork Reduction Act

The Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3507(d)) requires that CBP consider the impact of paperwork and other information collection burdens imposed on the public. An agency may not conduct, and a person is not required to respond to, a collection of information unless the collection of information displays a valid control number assigned by the Office of Management and Budget. There is no information collection associated with this pilot, so the provisions of the PRA do not apply.

Authorization for the Pilot

This pilot is being conducted in accordance with 19 CFR 101.9(a), which authorizes the Commissioner to impose requirements different from those specified in the CBP regulations for the purposes of conducting a test program or procedure designed to evaluate the effectiveness of new technology or operational procedures regarding the processing of passengers, vessels, or merchandise. For participants in this pilot, CBP will waive the requirements to pay tonnage tax, light money, COBRA user fees, AQI user fees, and navigation fees by cash or check at the time of arrival or when the applicable service is provided, if the participant has paid all applicable taxes and fees due online prior to the vessel's arrival or prior to the time the vessel is cleared by CBP. The pilot also permits CBP officers to process the payment of checks over

\$100 without obtaining authorization from the Customs officer in charge.

Dated: December 5, 2017.

Sean Mildrew,

Acting Assistant Commissioner, Office of Finance.

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DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Delay of Transition of the Generating, Transmitting and Updating of Daily and Monthly Statements from the Automated Commercial System to the Automated Commercial Environment

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Delay of transition of statement processing.

SUMMARY: On November 8, 2017, U.S. Customs and Border Protection (CBP) published a notice in the **Federal Register** announcing plans to make the Automated Commercial Environment (ACE) the sole electronic data interchange (EDI) system authorized by CBP for generating, transmitting, and updating daily and monthly statements for all entries except reconciliation (type 09) entries. The changes announced in that notice were to become operational on December 9, 2017. This notice announces that the date for the transition to ACE as the sole CBP-authorized EDI system for statement processing is delayed until January 6, 2018. ACE will not be the official system of records for statements until that time.

DATES: As of January 6, 2018, ACE will be the sole CBP-authorized EDI system for generating, transmitting, and updating daily and monthly statements, and the Automated Commercial System (ACS) will no longer be a CBP-authorized EDI system for such purpose.

FOR FURTHER INFORMATION CONTACT: For policy-related questions, contact Randy Mitchell, Commercial Operations, Revenue and Entry, Trade Policy and Programs, Office of Trade, via email at otentrysummary@cbp.dhs.gov, or telephone at (202) 863-6532. For technical questions, contact Celestine Harrell, Revenue Modernization Branch, Trade Transformation Office, Office of Trade, via email at Celestine.Harrell@cbp.dhs.gov, or telephone at (202) 325-0101, with a subject line identifier reading "Statement Processing in ACE".