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Pub. 100-04-Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Executive Guidance Number 0042	**Date: AUGUST 29, 2007**
Planned Web Site Address http://www.cms.hhs.gov/manuals/	**Release planned: 09/12/07**

PROGRAM AREA: Part B Drug Pricing

SUBJECT: October 2007 Quarterly Average Sales Price (ASP) Medicare Part B Drug Pricing Files and Revisions to Prior Quarterly Pricing Files

APPLIES TO: DMEPOS, Hospitals, Physicians, Non-Physician Practitioners

I. SUMMARY OF DOCUMENT: This CR announces the filenames for the quarterly ASP CRs and instructs the contractors to implement the files. The Oct - Dec 2007 ASP Pricing file and Not Otherwise Classified (NOC) Pricing files will be issued. Revised October 2006, January 2007, April 2007 and July 2007 ASP and NOC Pricing files will be issued as necessary

II. CHANGES IN POLICY INSTRUCTIONS: (If not applicable, indicate N/A)
STATUS: R=REVISED, N=NEW, D=DELETED.

Status	CHAPTER/SECTION/SUBSECTION/TITLE
N/A	

III. CLEARANCES:

Clearance & Point of Contact (POC)	Name/Telephone/Component
Senior Official Clearance	Liz Richter (410) 7896-0550 CMM
Agency POC	Catherine Jansto (410) 786-7762 CMM/HAPG/DAS

IV. TYPE (Check appropriate boxes for type of guidance)

	Audit Guide
X	Change Request
	HPMS
	Joint Signature Memorandum/Technical Director Letter
	Manual Transmittal/Non-Change Request
	State Medicaid Director Letters
	Other

V. STATUTORY OR REGULATORY AUTHORITY: Section 303(c) of the Medicare Modernization Act of 2003

Attachment – RECURRING UPDATE NOTIFICATION

Pub. 100-04	Transmittal:	Date:	Change Request: 5710

SUBJECT: October 2007 Quarterly Average Sales Price (ASP) Medicare Part B Drug Pricing Files and Revisions to Prior Quarterly Pricing Files

Effective Date: October 1, 2007

Implementation Date: October 1, 2007

I. GENERAL INFORMATION

A. Background: Section 303(c) of the Medicare Modernization Act of 2003 (MMA) revised the payment methodology for Part B covered drugs and biologicals that are not paid on a cost or prospective payment basis. Per the MMA, beginning January 1, 2005, the vast majority of drugs and biologicals not paid on a cost or prospective payment basis will be paid based on the average sales price (ASP) methodology. Pricing for compounded drugs is performed by the local contractor. Additionally, beginning in 2006, all ESRD drugs furnished by both independent and hospital-based ESRD facilities, as well as specified covered outpatient drugs, and drugs and biologicals with pass-through status under the Outpatient Prospective Payment System (OPPS), will be paid based on the ASP methodology. The ASP methodology is based on quarterly data submitted to CMS by manufacturers. CMS will supply contractors with the ASP drug pricing files for Medicare Part B drugs on a quarterly basis.

As announced in late 2006, the CMS has been working further to ensure that accurate and separate payment is made for single source drugs and biologicals as required by Section 1847A of the Social Security Act. As part of this effort, we have also reviewed how we have operationalized the terms "single source drug," "multiple source drug," and "biological product" in the context of payment under section 1847A. For the purposes of identifying "single source drugs" and "biological products" subject to payment under section 1847A, generally CMS (and its contractors) will utilize a multi-step process. We will consider:

- The FDA approval,
- Therapeutic equivalents as determined by the FDA, and
- The date of first sale in the United States.

For a biological product (as evidenced by a new FDA Biologic License Application or other relevant FDA approval) or a single source drug (that is, not a drug for which there are two or more drug products that are rated as therapeutically equivalent in the most recent FDA Orange Book) first sold in the United States after October 1, 2003, the payment limit for a biological product or single source drug will be based on the pricing information for products marketed or sold under the applicable FDA approval. As appropriate, a unique HCPCS code will be assigned to facilitate separate payment. Separate payment may be operationalized through use of "not otherwise classified" HCPCS codes.

For 2007, a separate fee of $0.152 per I.U. of blood clotting factor furnished is payable when separate payment for the blood clotting factor is made. The furnishing fee will be included in the payment amounts on the quarterly ASP pricing files.

B. Policy: Beginning January 1, 2005, in general, the payment allowance limits for Medicare Part B drugs and biologicals that are not paid on a cost or prospective payment basis are 106 percent of the ASP. Beginning January 1, 2006, in general, the payment allowance limits for ESRD drugs when

separately billed by freestanding and hospital-based ESRD facilities, as well as specified covered outpatient drugs, and drugs and biologicals with pass-through status under the OPPS, will be paid based on 106 percent of the ASP. CMS will update the payment allowance limits quarterly. There are exceptions to this general rule as summarized below.

(1) The payment allowance limits for blood and blood products (other than blood clotting factors) that are not paid on a prospective payment basis, are determined in the same manner the payment allowance limits were determined on October 1, 2003. Specifically, the payment allowance limits for blood and blood products are 95 percent of the average wholesale price (AWP) as reflected in the published compendia. The payment allowance limits will be updated on a quarterly basis. Blood and blood products furnished in the hospital outpatient department are paid under OPPS at the amount specified for the APC to which the product is assigned.

(2) The payment allowance limits for infusion drugs furnished through a covered item of durable medical equipment on or after January 1, 2005, will continue to be 95 percent of the AWP reflected in the published compendia as of October 1, 2003, unless the drug is compounded or the drug is furnished incident to a professional service. The payment allowance limits will not be updated in 2007. The payment allowance limits for infusion drugs furnished through a covered item of durable medical equipment that were not listed in the published compendia as of October 1, 2003, (i.e., new drugs) are 95 percent of the first published AWP unless the drug is compounded or the drug is furnished incident to a professional service.

(3) The payment allowance limits for influenza, Pneumococcal and Hepatitis B vaccines are 95 percent of the AWP as reflected in the published compendia except where the vaccine is furnished in a hospital outpatient department. Where the vaccine is administered in the hospital outpatient department, the vaccine is paid at reasonable cost.

(4) The payment allowance limits for drugs and biologicals that are not included in the ASP Medicare Part B Drug Pricing File or Not Otherwise Classified (NOC) Pricing File, other than new drugs that are produced or distributed under a new drug application (or other application) approved by the Food and Drug Administration, are based on the published wholesale acquisition cost (WAC) or invoice pricing, except under OPPS where the payment allowance limit is 95 percent of the published AWP. In determining the payment limit based on WAC, the contractors follow the methodology specified in Pub. 100-04, Chapter 17, Drugs and Biologicals, for calculating the AWP but substitute WAC for AWP. The payment limit is 100 percent of the lesser of the lowest-priced brand or median generic WAC. For 2006, the blood clotting furnishing factor of $0.146 per I.U. is added to the payment amount for the blood clotting factor when the blood clotting factor is not included on the ASP file. For 2007, the blood clotting furnishing factor of $0.152 per I.U. is added to the payment amount for the blood clotting factor when the blood clotting factor is not included on the ASP file.

At the contractors' discretion, contractors may contact CMS to obtain payment limits for drugs not included in the quarterly ASP or NOC files or otherwise made available by CMS on the CMS Web site. If the payment limit is available from CMS, contractors will substitute CMS-provided payment limits for pricing based on WAC or invoice pricing. CMS will provide the payment limits either directly to the requesting contractor or via posting an MS Excel file on the CMS Web site.

(5) The payment allowance limits for new drugs and biologicals that are produced or distributed under a new drug application (or other new application) approved by the Food and Drug Administration and that are not included in the ASP Medicare Part B Drug Pricing File or Not Otherwise Classified (NOC) Pricing File are based on 106 percent of the WAC, or invoice pricing if the WAC is not published, except under OPPS where the payment allowance limit is 95 percent of the published AWP. This policy applies only to new drugs that were first sold on or after January 1, 2005. At the contractors' discretion,

contractors may contact CMS to obtain payment limits for new drugs not included in the quarterly ASP or NOC files or otherwise made available by CMS on the CMS Web site. If the payment limit is available from CMS, contractors will substitute CMS-provided payment limits for pricing based on WAC or invoice pricing. CMS will provide the payment limits either directly to the requesting contractor or via posting an MS Excel file on the CMS Web site. For 2006, the blood clotting furnishing factor of $0.146 per I.U. is added to the payment amount for the blood clotting factor when the blood clotting factor is not included on the ASP file. For 2007, the blood clotting furnishing factor of $0.152 per I.U. is added to the payment amount for a new blood clotting factor when a new blood clotting factor is not included on the ASP file.

(6) The payment allowance limits for radiopharmaceuticals are not subject to ASP. Contractors should determine payment limits for radiopharmaceuticals based on the methodology in place as of November 2003 in the case of radiopharmaceuticals furnished in other than the hospital outpatient department. Radiopharmaceuticals furnished in the hospital outpatient department are paid charges reduced to cost by the hospital's overall cost to charge ratio.

On or after September 18, 2007, October 2007 ASP file will be available for download. On or after September 18, 2007, revised January 2007, April 2007, July 2007 and October 2006 ASP payment files will be available for download if CMS determines that revisions to these files are necessary. Contractors will receive notification of the ASP NOC files from CMS. In addition, on or after September 18, 2007, the October 2007 ASP NOC files will be available on the CMS ASP Web page. On or after September 18, 2007, revised January 2007, April 2007, July 2007 and October 2006 ASP NOC files will be available on the CMS ASP Web page if CMS determines that revisions to these files are necessary. The revised payment files will be applied to claims processed or reprocessed on or after the effective date of this Change Request.

The October 2007 payment allowance limits apply to dates of service October 1, 2007, through December 31, 2007. If made available, the revised January 2007 payment allowance limits apply to dates of service January 1, 2007, through March 31, 2007; the revised April 2007 payment allowance limits apply to dates of service April 1, 2007, through June 30, 2007; the revised July 2007 payment allowance limits apply to dates of service July 1, 2007, through September 30, 2007; and the revised October 2006 payment allowance limits apply to dates of service October 1, 2006, through December 31, 2006.

The payment limits included in revised ASP and NOC payment files supersede the payment limits for these codes in any publication published prior to this document.

NOTE: The absence or presence of a HCPCS code and its associated payment limit does not indicate Medicare coverage of the drug or biological. Similarly, the inclusion of a payment limit within a specific column does not indicate Medicare coverage of the drug in that specific category. The local Medicare contractor processing the claim shall make these determinations.

Drugs Furnished During Filling or Refilling an Implantable Pump or Reservoir

Physicians (or a practitioner described in Section 1842(b) (18) (C)) may be paid for filling or refilling an implantable pump or reservoir when it is medically necessary for the physician (or other practitioner) to perform the service. Contractors must find the use of the implantable pump or reservoir medically reasonable and necessary in order to allow payment for the professional service to fill or refill the implantable pump or reservoir and to allow payment for drugs furnished incident to the professional service. If a physician (or other practitioner) is prescribing medication for a patient with an implantable pump, a nurse may refill the pump if the medication administered is accepted as a safe and effective treatment of the patient's illness or injury; there is a medical reason that the medication cannot be taken orally; and the skills of the nurse are needed to infuse the medication safely and effectively.

This instruction clarifies that payment for drugs furnished incident to the filling or refilling of an implantable pump or reservoir is determined under the ASP methodology, as described above unless the drugs furnished incident to the filling or refilling of an implantable pump or reservoir is a compounded drug, then pricing is performed by the local contractor.

II. BUSINESS REQUIREMENTS TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)										
		A/B MAC	DME MAC	FI	CARRIER	DMERC	RHHI	Shared-System Maintainers				OTHER
								FISS	MCS	VMS	CWF	
5710.1	The October 2007 and, if released, the revised January 2007, April 2007, July 2007 and October 2006 ASP drug pricing files for Medicare Part B drugs will be available via the CMS Data Center (CDC).	X	X	X	X	X	X	X	X	X		
5710.1.1	Contractors shall download the October 2007 ASP drug pricing file through the CDC on or after September 18, 2007. Final File: MU00.@BF12390.ASP.CY07.OCT.V0918	X	X	X	X	X	X	X	X	X		
5710.1.2	Contractors shall receive notification from CMS of the October 2007 ASP NOC pricing file.	X	X		X	X	X					
5710.1.3	Contractors shall use the October 2007 ASP and NOC drug pricing files to determine the payment limit for claims for separately payable Medicare Part B drugs processed or reprocessed on or after October 1, 2007 with dates of service October 1, 2007, through December 31, 2007.	X	X		X	X	X	X	X	X		
5710.1.4	Contractors shall use the October 2007 ASP drug pricing file to determine the payment limit for claims for separately payable Medicare Part B drugs processed or reprocessed on or after October 1, 2007 with dates of service October 1, 2007, through December 31, 2007.	X		X								
5710.1.5	If released by CMS, contractors shall download the revised July 2007 ASP drug pricing file through the CDC on or after September 18, 2007. Final File: MU00.@BF12390.ASP.CY07.JUL.V0918	X	X	X	X	X	X	X	X	X		

Number	Requirement	Responsibility (place an "X" in each applicable column)										
		A/B MAC	DME MAC	FI	CARRIER	DMERC	RHHI	Shared-System Maintainers				OTHER
								FISS	MCS	VMS	CWF	
5710.1.6	If released by CMS, contractors shall overlay or manually update the previous July 2007 file with the new July 2007 ASP drug pricing file.	X	X	X	X	X	X	X	X	X		
5710.1.7	If released by CMS, contractors shall use the revised July 2007 ASP drug pricing file to determine the payment limit for claims for separately payable Medicare Part B drugs processed or reprocessed on or after October 1, 2007 with dates of service July 1, 2007, through September 30, 2007.	X	X	X	X	X	X	X	X	X		
5710.1.8	If released by CMS, contractors shall receive notification from CMS of the revised July 2007 ASP NOC pricing file.	X	X		X	X	X					
5710.1.9	If released by CMS, contractors shall use the revised July 2007 ASP NOC pricing file to determine the payment limit for claims for separately payable Medicare Part B drugs processed or reprocessed on or after October 1, 2007 with dates of service July 1, 2007, through September 30, 2007.	X	X		X	X	X	X	X	X		
5710.1.10	If released by CMS, contractors shall download the revised April 2007 ASP drug pricing file through the CDC on or after September 18, 2007. Final File: MU00.@BF12390.ASP.CY07.APR.V0918	X	X	X	X	X	X	X	X	X		
5710.1.11	If released by CMS, contractors shall overlay or manually update the previous April 2007 file with the new April 2007 ASP drug pricing file.	X	X	X	X	X	X	X	X	X		
5710.1.12	If released by CMS, contractors shall use the revised April 2007 ASP drug pricing file to determine the payment limit for claims for separately payable Medicare Part B drugs processed or reprocessed on or after October 1, 2007 with dates of service April 1, 2007, through June 30, 2007.	X	X	X	X	X	X	X	X	X		
5710.1.13	If released by CMS, contractors shall receive notification from CMS of the revised April 2007 ASP NOC pricing file.	X	X		X	X	X					
5710.1.14	If released by CMS, contractors shall use the revised April 2007 ASP NOC pricing file to	X	X		X	X	X	X	X	X		

Number	Requirement	Responsibility (place an "X" in each applicable column)										
		A/B MAC	DME MAC	FI	CARRIER	DMERC	RHHI	Shared-System Maintainers				OTHER
								FISS	MCS	VMS	CWF	
	determine the payment limit for claims for separately payable Medicare Part B drugs processed or reprocessed on or after October 1, 2007 with dates of service April 1, 2007, through June 30, 2007.											
5710.1.15	If released by CMS, contractors shall download the revised January 2007 ASP drug pricing file through the CDC on or after September 18, 2007. Final File: MU00.@BF12390.ASP.CY07.JAN.V0918	X	X	X	X	X	X	X	X	X		
5710.1.16	If released by CMS, contractors shall overlay or manually update the previous January 2007 file with the new January 2007 ASP drug pricing file.	X	X	X	X	X	X	X	X	X		
5710.1.17	If released by CMS, contractors shall use the revised January 2007 ASP drug pricing file to determine the payment limit for claims for separately payable Medicare Part B drugs processed or reprocessed on or after October 1, 2007 with dates of service January 1, 2007, through March 31, 2007.	X	X	X	X	X	X	X	X	X		
5710.1.18	If released by CMS, contractors shall receive notification from CMS of the revised January 2007 ASP NOC pricing file.	X	X		X	X	X					
5710.1.19	If released by CMS, contractors shall use the revised January 2007 ASP NOC pricing file to determine the payment limit for claims for separately payable Medicare Part B drugs processed or reprocessed on or after October 1, 2007 with dates of service January 1, 2007, through March 31, 2007.	X	X		X	X	X	X	X	X		
5710.1.20	If released by CMS, contractors shall download the revised October 2006 ASP drug pricing file through the CDC on or after September 18, 2007. Final File: MU00.@BF12390.ASP.CY06.OCT.V0918	X	X	X	X	X	X	X	X	X		
5710.1.21	If released by CMS, contractors shall overlay or manually update the previous October 2006 file with the new October 2006 ASP drug pricing file.	X	X	X	X	X	X	X	X	X		
5710.1.22	If released by CMS, contractors shall use the	X	X	X	X	X	X	X	X	X		

Number	Requirement	Responsibility (place an "X" in each applicable column)										
		A/B MAC	DME MAC	FI	CARRIER	DMERC	RHHI	Shared-System Maintainers				OTHER
								FISS	MCS	VMS	CWF	
	revised October 2006 ASP drug pricing file to determine the payment limit for claims for separately payable Medicare Part B drugs processed or reprocessed on or after October 1, 2007, with dates of service October 1, 2006, through December 31, 2006.											
5710.1.23	If released by CMS, contractors shall receive notification from CMS of the revised October 2006 ASP NOC pricing file.	X	X		X	X	X					
5710.1.24	If released by CMS, contractors shall use the revised October 2006 ASP NOC pricing file to determine the payment limit for claims for separately payable Medicare Part B drugs processed or reprocessed on or after October 1, 2007 with dates of service October 1, 2006, through December 31, 2006.	X	X		X	X	X	X	X	X		
5710.2	Contractors shall not search and adjust claims that have already been processed unless brought to their attention.	X	X	X	X	X	X	X	X	X		
5710.3	Notification of successful receipt shall be sent via e-email to price_file_receipt@cms.hhs.gov stating the name of the file received and the entity for which it was received (e.g., carrier/DMERC/fiscal intermediary name and number).	X	X	X	X	X	X	X	X	X		
5710.4	The ASP and NOC drug pricing files will contain the applicable payment allowance limits (i.e., 106% ASP, 106% WAC, or 95% AWP); therefore, Medicare contractors shall not make any additional payment calculations.	X	X	X	X	X	X	X	X	X		
5710.5	For any drug or biological not listed in the ASP or NOC drug pricing files, contractors shall determine the payment allowance limits in accordance with the policy described in this CR and JSM-06391.	X	X	X	X	X	X	X	X	X		
5710.5.1	FIs should seek payment allowances not on the ASP file from their local carrier for drugs and biologicals.	X		X			X	X				
5710.6	At the contractor's discretion, contractors should contact CMS to obtain payment limits for drugs not included in the quarterly ASP or	X	X	X	X	X	X					

Number	Requirement	Responsibility (place an "X" in each applicable column)										
		A/B MAC	DME MAC	FI	CARRIER	DMERC	RHHI	Shared-System Maintainers				OTHER
								FISS	MCS	VMS	CWF	
	NOC files or otherwise made available by CMS on the CMS Web site.											
5710.6.1	If the payment limit is available from CMS, contractors shall substitute CMS-provided payment limits for pricing, based on WAC or invoice pricing.	X	X	X	X	X	X	X	X	X		
5710.6.1.1	Contractors shall contact CMS via e-mail at sec303aspdata@cms.hhs.gov.	X	X	X	X	X	X					
5710.6.1.2	Contractors shall include "Pricing Request" in the subject line.	X	X	X	X	X	X					
5710.7	Contractors shall use the most current version available of the Medicare Contractor Reporting Template for Part B drugs to report information on Medicare Part B drugs not paid on a cost or prospective payment basis when payment limits are not listed in the quarterly drug pricing ASP and NOC files, or in the OPPS Pricer.	X	X	X	X	X	X					
5710.7.1	Contractors shall use the template to report pricing information for the NOC drugs not included on the Medicare Part B NOC pricing file, any HCPCS drug codes not on the ASP file, and OPPS drugs not in the OPPS Pricer.	X	X	X	X	X	X					
5710.7.2	Contractors shall list all drugs that were priced since the last submitted report.	X	X	X	X	X	X					
5710.7.3	Contractors shall list each drug priced on the report only once, unless the drug was priced via invoice and the price is not the same.	X	X	X	X	X	X					
5710.7.4	For compounded drugs, contractors shall report the name of each drug in the compounded product that required manual pricing.	X	X	X	X	X	X					
5710. 7.5	Contractors shall prepare and submit the reports so that each report covers approximately 30 days of pricing activity.	X	X	X	X	X	X					
5710.7.6	Contractors shall report drugs omitted from previous reports in the next report.	X	X	X	X	X	X					
5710.7.7	Contractors shall complete the report in its entirety.	X	X	X	X	X	X					
5710.7.8	Carriers do not need to report radiopharmaceuticals.	X	X	X	X	X	X					
5710.7.9	FIs shall report pricing information for drugs, biologicals, and radiopharmaceuticals that are	X		X			X					

Number	Requirement	Responsibility (place an "X" in each applicable column)										
		A/B MAC	DME MAC	FI	CARRIER	DMERC	RHHI	Shared-System Maintainers				OTHER
								FISS	MCS	VMS	CWF	
	billed using C9399.											
5710.8	Contractors shall download the most current version available of the template from the CMS Web site at http://www.cms.hhs.gov/McrPartBDrugAvgSalesPrice/02_aspfiles.asp.	X	X	X	X	X	X					
5710.9	Contractors shall complete the template on a monthly basis.	X	X	X	X	X	X					
5710.9.1	The template shall be in MS Excel format.	X	X	X	X	X	X					
5710.9.2	Contractors shall send it to sec303aspdata@cms.hhs.gov on the first business day of the month.	X	X	X	X	X	X					
5710.9.3	If the contractor has not priced any drugs since the last submitted report, in lieu of using the template, the contractor shall send an email to Sec303aspdata@cms.hhs.gov stating that the contractor has no drug pricing to report.	X	X	X	X	X	X					

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)										
		A/B MAC	DME MAC	FI	CARRIER	DMERC	RHHI	Shared-System Maintainers				OTHER
								FISS	MCS	VMS	CWF	
5710.10	A provider education article related to this instruction will be available at http://www.cms.hhs.gov/MLNMattersArticles/ shortly after the CR is released. You will receive notification of the article release via the established "MLN Matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web site and include information about it in a listserv message within one week of the availability of the provider education article. In addition, the provider education article shall be included in your next regularly scheduled bulletin. Contractors are free to supplement MLN Matters	X	X	X	X	X	X					

Number	Requirement	Responsibility (place an "X" in each applicable column)										
		A/B MAC	DME MAC	FI	CARRIER	DMERC	RHHI	Shared-System Maintainers				OTHER
								FISS	MCS	VMS	CWF	
	articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.											

IV. SUPPORTING INFORMATION

A. Recommendations and supporting information associated with listed requirements:
"Should" denotes a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:
	N/A

B. Other recommendations and supporting information: N/A

V. CONTACTS

Pre-Implementation Contact(s): Glenn McGuirk, glenn.mcguirk@cms.hhs.gov

Post-Implementation Contact(s): Glenn McGuirk, glenn.mcguirk@cms.hhs.gov

VI. FUNDING

A. *For Fiscal Intermediaries, Carriers, and the Durable Medical Equipment Regional Carrier (DMERC)*:
No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 2008 operating budgets.

B. *For Medicare Administrative Contractors (MAC)*:

The contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the Statement of Work (SOW). The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.