SelfMonitoring Blood Glucose System (SMBGS) Test Strip CLASS QUESTIONS FY15Q1	
QUESTIONS	**ANSWERS**
1. Will the BPA awarded pursuant to this solicitation be a single- or multi-award BPA? If it will be a multi-award BPA, how many awardees will DHA select?	BPAs will be awarded based on the uniform formulary decision. See SMBGS Test Strip UF Solicitation Appendix.
2. The BPA and VARR appendices issued in connection with this solicitation do not contain an explicit requirement that meters be TAA compliant—instead, these appendices merely require that meters be made available to DHA at "no cost."	
A. Are meters being acquired by DHA pursuant to this BPA and the contracts issued under this BPA?	DoD is not soliciting quotes for meters. See SMBGS Test Strip UF Solicitation Appendix, SMBGS Test Strips BPA Performance Terms/Conditions: "In accordance with industry practice, the Company shall make meters available to DoD beneficiaries at no additional charge or cost to the DoD beneficiary."
B. Are these "no cost" meters required to be TAA compliant? If so, at what time must compliance be demonstrated (e.g., at time of offer, time of award, or time of implementation)?	The solicitation does not contain DoD terms, conditions, criteria, or requirements regarding the Buy American Act and Trade Agreements Act. DoD does not provide legal advice to potential offerors on their obligations, if any, to comply with the requirements of the Buy American Act and Trade Agreements Act.
3. The BPA solicitation requires that the "Company must have an existing FSS contract for any pharmaceutical agent(s) quoted in this UFBPA at the time the quote is submitted, and at the time the UFBPA is executed." Are companies that submit an offer in response to this solicitation required to have an existing FSS contract for the "no cost" meters referred to in the BPA and VARR appendices?	The solicitation is seeking quotes for test strips via BPA under the FSS. DoD is not soliciting quotes for meters; therefore, a BPA is not being established for meters and an FSS for meters is not relevant or required. See SMBGS Test Strip UF Solicitation Appendix, SMBGS Test Strips BPA Performance Terms/Conditions: "In accordance with industry practice, the Company shall make meters available to DoD beneficiaries at no additional charge or cost to the DoD beneficiary."
4. The previous solicitation issued by DHA for test strips and meters was not issued until the completion of a series of meetings and correspondence between manufacturers and DHA, specifically with the Pharmacoeconomic Center ("PEC") and Pharmacy and Therapeutics Committee ("P&T Committee").	
A. Will there be similar opportunity to meet with the PEC and the P&T Committee in	No, there will be no face to face meetings at the PEC for this solicitation. As specified on the solicitation

connection with this solicitation?	web site, manufacturers may send information to the PEC email address at usarmy.jbsa.medcom-ameddcs.list.pecuf2@mail.mil.
B. Will there be an opportunity to include program value ads (e.g. You Choose Wellness and Support Program - available teaching tools for Educators to use with their patients) to the P&T Committee for review with the overall manufacturing offer? If so, where would this additional information be provided within the current solicitation since there is no identified section?	As noted on the solicitation webpage, all information manufacturers wish to be considered for this solicitation should be submitted by 17 Oct 2014 to usarmy.jbsa.medcom-ameddcs.list.pecuf2@mail.mil.
C. Will there be an evaluation of the meters and strips? If so what type of evaluation (e.g., a "hands-on" evaluation)?	In accordance with 32 CFR 199.21(e)(1), the Pharmacy and Therapeutics Committee will consider pertinent information from a variety of sources determined by the Committee to be relevant and reliable.
D. If there is not an evaluation, by what terms or standards will strips and meters be evaluated for technical capability?	See answer to question 4.C.
E. Will the P&T Committee have access to any technical evaluations and/or recommendations that were made under the 2013 BPA solicitation that remains open?	See Answer to question 4.C.
5. Does the DHA intend to formally cancel the impending BPA solicitation that is still open from calendar year 2013?	There is not an impending BPA solicitation open from calendar year 2013.
6. Please define further what is meant by the term "suite" as set forth in the UF BPA Solicitation Appendix. May a suite contain more than one strip, and more than one meter, provided that all strips within the suite have the same price?	Each company designates what strips are in the company's group of strips known as a suite. A suite may contain more than one strip provided all strips within the suite have the same price. Yes
7. Please define further the class notes within the BPA solicitation, "Companies may only submit one suite and only one quoted price per condition set category". Does this mean that all quoted prices per condition set category must be the same or can a different price be quoted within each condition set provided the strips within the suite have the same price?	Within a condition set, prices for each SMBG test strip included in the suite must be the same. Prices may vary from condition set to condition set.

8. How will strips be procured (e.g. prime vendor or direct with manufacturer or both)?	See paragraph 4 and 5 of the BPA.
9. On what day within the calendar quarter (e.g. last Thursday of the quarter) will published WAC data be pulled from clearinghouses for the purpose of calculating and filing of quarterly rebate claims under UF VARR?	The Government will not provide and commit to this level of specificity regarding the cost evaluation.
10. How is "medical necessity" defined as an exception to the no grandfathering requirement? Would a talking meter for visually impaired individuals meet the definition?	Medical necessity, if any, will be defined by the Committee and approved by the Director, DHA. Possible examples are listed on the BPA appendix.
11. How is "adequate trial" defined as being a requirement prior to exception being made for a non- preferred product? Must the trial of the preferred product be used for a minimum of 30 days, 60 days, etc.?	The length of an adequate trial, if any, will be defined by the Committee and approved by the Director, DHA.
12. The UF BPA and the UF VARR Appendices state that "Each company designates what strips are in the company's group of strips known as a suite. Please confirm that:	
A. A manufacturer does not have to offer every product currently listed in the utilization dataset in both its BPA and VARR quotes	Correct, the company designates what brand name strips are in the suite.
B. If an item has distinct NDC's for purchase by institutional customers (MTF and TMOP) and retail customers (Tricare network pharmacies), the BPA and VARR price quotes need only include the NDC's in the utilization data set for that item applicable to those customers	The company designates what brand name strips are in the suite. The BPA quote must include all NDCs on the company's FSS associated with the designated brand name strips in the company's suite. Further, all NDCs in the BPA quote must be on the FSS as the BPA quote may not contain NDCs that are not on the FSS. At a minimum, the VARR quote must include all NDCs included in the utilization data set associated with the designated brand name strips in the company's suite, including the NDCs on the company's FSS associated with the designated brand name strips in the company's suite (all NDCs in the BPA quote). Since BPAs may not include NDCs that are not on the FSS, it is feasible that the VARR quote may have more NDCs than the BPA quote if designated brand name strips in the suite include

	distinct retail NDCs that are not on the FSS.
13. Is there a requirement to provide TAA compliant meters as part of a successful contract, or is that no longer a criteria?	This solicitation does not contain DoD terms, conditions, criteria, or requirements regarding the Buy American Act and Trade Agreements Act. DoD does not provide legal advice to potential offerors on their obligations, if any, to comply with the requirements of the Buy American Act and Trade Agreements Act.
14. Can manufacturers submit price quotes for only one "instrument" (UF BPA or UF VARR)? For example, can a vendor only submit pricing for the UF VARR and not the UF BPA? Or does vendor have to submit pricing for both UF BPA and UF VARR? Are the two tied together in the Committee's evaluation?	There is not a requirement to submit both a BPA quote and a VARR quote. In considering relative cost effectiveness in accordance with 32 CFR 199.21(e)(2) and as specified in the solicitation, for cost of the pharmaceutical agent to the Government, the Evaluation Price for this class will be: • For the MTF and Mail dispensing venues - The lower of: o A UF BPA price quote o Big 4 FSS price as listed on the first day of the month preceding the DoD P&T meeting. • For the Retail dispensing venue- The lower of: o UF VARR calculated refund o Absent a UF VARR Quote, the current price as of the first day of the month preceding the DoD P&T meeting.
15. Reference to the UF BPA and the UF VARR, paragraphs four (4) and nine (9) on page two (2) of the document titled "DoD P&T Committee Evaluation of the Class SMBG" states "The DoD reserves the right to exclude specific formulations of a given class or agent from a submitted quote…"Please clarify if there would be any limitations to these rights to exclude or any rationale to justify excluding a specific class or agent.	Since the offeror defines a suite, it is unlikely that the DoD will exclude a specific agent, but reserves the right to do so for cause and will not be arbitrary.
16. Regarding Performance Terms/Conditions in the appendices for the UF BPA and UF VARR, how will the DoD verify that the Company has test strips available at each POS?	The agency will not limit itself to any specific surveillance techniques to ensure performance requirements are met.
17. For each condition set listed in the appendices for the UF BPA and UF VARR, could DoD quantify its market share expectations for the formulary agents?	No
18. Is it a requirement to include a price quote for each condition set?	A company may submit quotes for one or more condition sets, or none at all.

19. May we submit binders for the P&T Committee, in addition to the required email submission?	As noted on the solicitation webpage, all information manufacturers wish to be considered for this solicitation should be submitted by 17 Oct 2014 to usarmy.jbsa.medcom-ameddcs.list.pecuf2@mail.mil.
20. When will pricing load for all 3 POS?	See paragraph 4 of the BPA.
21. Can you provide a more detailed description of grandfathering expectations? For example, does it cover renewals/refills for prescriptions written before the new BPA is effective, or will it include new prescriptions written after the BPA is effective? Is there a cut-off date, or can a patient be indefinitely grandfathered in?	Grandfathering of patients, if any, will be defined by the Committee and approved by the Director, DHA.
22. When will step-edits and/or NDC blocks go into effect for MTF, TMOP, and Retail POS? What is the nature of these controls, if any?	Implementation period is determined by the Committee and approved by the Director, DHA. The Government will not provide and commit to this level of specificity regarding the nature of the controls.
A. For the condition sets where grandfathering applies, do the normal UF rules still apply to NF agents, i.e., Tier 3 co-pay and accessibility limits?	Yes
B. After step therapy, are MTFs free to stock and dispense any strip as back up or must it be a Tier 2 strip? Will there be a co-pay?	MTFs must stock the BCF strip. Local P&T committees will determine local formulary status of other UF designated strips regardless of step positions. There are no copays in the MTFs
C. Will beneficiaries pay the NF co-pay in the Retail and TMOP POS?	See answer to question 22.A.