Response to Comments Received to the 2nd edition of Standards for a Patient Blood Management Program

Please note that public comments that were submitted address the proposed 2nd edition of PBM Standards, and not the final version. The changes are best understood when the proposed Standards are compared to the final published version. The program unit has elected to make the substance of public comments that were submitted a part of this document. This document does not represent a full summary of significant changes to the 2nd edition of PBM Standards. Guidance that appears with the 2nd edition of PBM Standards in the Standards Portal provides a more in-depth look at the additions, deletions and changes and the rationales behind those decisions that what appears below.

Standard	RC/SC	Comment	Change made?	Outcomes
1.1.2.1, #11 (1.1.2.1, #12)	RC	This reflects identification of such patients who refuse blood transfusion rightfully remains a requirement for all Activity Levels. What does a formal program entail? In our opinion, a "formal program to care for patients who decline blood or blood-derived products" is indicative of a fully operational clinical program that includes protocols and resources for the care and therapeutic management of such patients. Is the expectation that regardless of Activity level, the institution must have such a program for caring for these patients where the management can require extensive resources and expertise? For each of the Activity levels, achieving this would involve a different process. A formal program for a level 1 could have a coordinator but a program with an Activity Level 3 would not be able to sustain or even have the financial and personnel resources for such a "formal" program. We recommend that this item be returned to a requirement for only Activity Level 1 institutions.	No	The committee noted this comment but did not feel that a change was needed. The committee will expand on this issue in guidance.
1.1.2.1, #13 (New)	RC	How would an evidenced-based massive transfusion protocol be demonstrated for Activity Level 2 and Level 3 institutions? Could a transfusion service SOP be used as evidence for issuing blood products for an MTP/massively bleeding patient when there is not a robust MTP protocol at the institution (especially if the hospital is small with limited staff to run an MTP and then they ship the patient to a larger facility).It would be difficult for small critical-access hospitals or 30-50 bed hospitals who desire to become PBM certified under Activity Level 3 to implement an "evidence based" massive transfusion protocol since plasma, cryoprecipitate or platelet components are not routinely stocked at such facilities. Comments should be added into Guidance for achieving this standard where the massive transfusion protocol correlates with the facility-designated trauma level.	No	The committee noted this comment but feels that having a validated massive transfusion protocol should be something that all programs have, at all levels. When being assessed, the program should be able to show that the process in place ensures that timely

				delivery of a component and that the process has been validated and shown to be effective.
1.1.2.1, #15 (1.1.2.1, #14)	RC	What is the rationale for eliminating anemia management for a level 2 and 3 facility? The literature clearly supports roughly 30% of the patient population is anemic. If healthcare is going to reach six sigma like aviation, we must demand proactive standards. To me, this seems to be as basic as an aviation take off check list.	No	The committee reviewed this comment and felt that an anemia management plan should remain with level 1 and 2 programs. There are programs of smaller sizes that do not have the resources to meet this requirement.
1.1.2.1, #16 (1.1.2.1, #15)	RC	We oppose the expansion of Item #15 to all Activity levels (see discussion below) and request that additional details and comments be put into the guidance document for these Standards for meeting this particular standard in relation to the expectation of each Activity Level for the items listed.	Yes	The committee agreed with the request made by the commenter to revert Item 15 in the proposed edition, now item 16 to a requirement for only level 1 and 2 programs.
5.2 (5.3.4)	RC	I think standard 5.3.4 should not be restricted to "Pre- and Posttransfusion Patient Care". Shouldn't this Standard stand alone and be at the same hierarchy as Standard 5.3? Thus, suggest make this Standard 5.3 and then the "Pre- and Posttransfusion Patient Care" (and substandards) 5.4 and so on.	Yes	The committee noted this comment and agreed with the intent of the comment and moved the standard to now appear as new standard 5.2.
5.2 (5.3.4)	RC	This should be a standalone standard and not a substandard under 5.3. Institutions should review, revise or create policies, process and procedures that minimize blood loss during phlebotomy for laboratory testing for all patients even if they do not receive a transfusion. With the placement of this standard as a substandard of 5.3, it implies that this is restricted to "Pre and Post transfusion Patient Care".	Yes	The committee noted this comment and made the change requested making the standard a stand alone standard as new standard 5.2.

5.5.3 (5.3.3)	RC	What is the supportive evidence of over transfusion or under transfusion? This seems subjective	No	The committee noted this comment but did not feel an edit was needed and notes that there is a large amount of literature and evidence to support the inclusion of this standard.
5.6.2 (5.4.2)	RC/SC	We recommend that the word procedure be changed to process. Procedure as defined in the glossary is a series of tasks usually performed by one person according to instructions. This definition implies a written document would need to be in place with instructions for the staff. Process, as defined in the glossary, is a set of related tasks and activities that accomplish a work goal. By using the word process in this standard, particularly for subsection items 2 and 4 through 7, institutions would be able to show a process for using tasks and activities to meet those subsections that use the wording Assessments and Considerations.	Yes	The committee noted this comment and edited the stem of this standard to include "processes and/or procedures" to ensure that the entire list is covered.
5.7 (New)	RC	This standard should be clarified. The standard conflicts with item #20 in 1.1.2.1 which is only for Activity Level 1. Or, does this newly added standard only apply to an Activity Level 1 institution? In the comments for this standard it is stated that the standard is new to the proposed edition and was included to clarify the relationship between the PBM program and the activities covered in AABB's Perioperative Standards. It should be further clarified that these two groups should be working in conjunction with each other. The standard as written indicates that the program shall review all of the 9 intraoperative methods listed. Institutions at the 3 Activity Levels may not perform all 9 intraoperative methods. Therefore, how does an institution review a method that they do not perform? If the committee intends for institutions at all activity levels to meet this standard then there needs to be guidance for complying with this standard. We would also like clarification on how the committee intends for the program to audit itself with respect to these methods and how an external assessment of the program would be completed if the institution does not perform a method listed.	Yes	The committee noted this comment and has moved the bulk of the standard, specifically the list, to appear in guidance. The standard has now been modified to require that patient blood management programs review methods for minimizing blood loss during surgery or invasive procedures.
5.10 (5.7)	RC	Regarding Massive Blood Loss and Emergent Care timely delivery of blood components for patients experiencing massive bleeding is subjective. A problem we are working on is massive transfusion protocol called in surgery should include use of cell salvage equipment	Yes	The committee agreed with this comment and edited the standard to remove the term "protocol" and replaced it

				with “processes and procedures.”
6.2.2.1	RC	The standard begins with the statement that the program shall have access to patient records. Then the standard switches to using the term record system. Does this refer to any record system that the institution uses or the patient record system? Investigations into adverse events are not routinely documented in a patient record. Please add the word for in the last line of the standard. “The record system shall allow for the evaluation….”	No	The committee noted this comment but did not feel that the standard as written needed to be edited further. The committee feels that the program record system must allow for traceability for all patients from the start of the process to its termination.