PROPOSED Standards for a Patient Blood Management Program, 4th Edition

A Note to Readers

Individuals not familiar with the standards-setting practices of AABB should be aware of the following:

• Requirements, once stated, are not repeated. For example, standard 5.0 requires that all processes and procedures be validated. Therefore, it is not necessary to require in other areas that a specific process or procedure be validated.
• Words or phrases used in a way different from their usual meaning are defined in the glossary.
• The term "specified requirements" is defined broadly to include accreditation requirements, national, state, or local laws, and any other applicable requirement.
• Please note, that the Summary of Significant Changes to the proposed 4th edition begins on page 2 and runs through page 13.

The proposed 4th edition begins on page 14 and runs through page 54.

Significant Changes to the Proposed 4th edition of Standards for a Patient Blood Management Program

1.1.1 Medical Director Qualifications and Responsibilities
The program shall have a medical director who is a licensed **provider/** physician and qualified by education, training, and/or experience.

The committee added the term in bold for completeness.

Item	Responsibility	Activity Level 1	Activity Level 2	Activity Level 3
2	Metrics regarding transfusion appropriateness **consistent with** ~~in accordance with~~ transfusion guidelines.	X	X	X

The committee replaced the term "in accordance with" with "consistent with" for clarity.

Item	Responsibility	Activity Level 1	Activity Level 2	Activity Level 3
8	Pre-procedure **assessment and management** ~~optimization~~ of patient coagulation **status** ~~function~~.	X	X	X

The committee added the clause "assessment and management" for clarity. The term "status" replaced "function" for accuracy.

Item	Responsibility	Activity Level 1	Activity Level 2	Activity Level 3

10	Minimize blood loss due to laboratory testing. **(iatrogenic blood loss)**	X	X	X

The committee added the clause in parentheses for completeness.

Item	Responsibility	Activity Level 1	Activity Level 2	Activity Level 3
12	Processes to identify, before or upon admission, patients who may decline transfusion ~~under any circumstances~~ with notification to the appropriate individuals **(including providers) and noted in the patient's medical record.**	X	X	X

The committee removed the clause "under any circumstances" as it was deemed not relevant. The addition of the parenthetical "including providers) and "and noted in the patient's medical record" was included for completeness.

Item	Responsibility	Activity Level 1	Activity Level 2	Activity Level 3
13	Massive transfusion protocol **for all patient populations** with documented **evaluation of activation and protocol workflow effectiveness** ~~evidence of its use~~.	X	X	X

The committee added the clause in bold for clarity, ensure that all patient populations served by the program are considered in their massive transfusion protocols and that the activation was effective.

Item	Responsibility	Activity Level 1	Activity Level 2	Activity Level 3
15	PBM care for obstetric patients including postpartum hemorrhage protocol with evidence of its use, plan(s) for patients with known high bleeding risk (eg, placental abnormalities), and plans for patients **who decline blood** ~~for whom blood is not an option~~	X	X	X

The committee replaced the clause "for whom blood is not an option" with "who decline blood" for legibility. The change has been made throughout the document wherever this terminology is used.

Item	Responsibility	Activity Level 1	Activity Level 2	Activity Level 3
16	Single-unit transfusion strategies for defined **clinical settings** ~~patient population(s)~~.	X	X	X

The committee replaced the term "patient population(s)" with "clinical settings" for clarity as this instance is defined by the clinical situation vs the patient.

Item	Responsibility	Activity Level 1	Activity Level 2	Activity Level 3
20	Evaluating and managing iron and micronutrient deficiencies in ~~defined~~ patients with Red Blood Cells ordered in the **inpatient and** outpatient **populations** ~~settings~~.	X	X	N/A

The committee removed the term "defined" as the committee deemed it unnecessary with the inclusion of the clause "…inpatient and…" to ensure that the full patient population served by the Standards are covered in the chart.

Item	Responsibility	Activity Level 1	Activity Level 2	Activity Level 3
21	Evaluation and management of identified anemia in ~~non-operative~~ patients.	X	N/A	N/A

The committee edited entry 21 to reflect that this requirement applies to more than just nonoperative patients.

Item	Responsibility	Activity Level 1	Activity Level 2	Activity Level 3
23	Identification and management of presurgical anemia before elective procedures for patients at risk for red	X	N/A	N/A

	blood cell transfusion and/or adverse consequences of post-surgical anemia ~~which type and screen or type and crossmatch is recommended~~			

The committee replaced the clause in strikethrough with the clause in bold for clarity.

Item	Responsibility	Activity Level 1	Activity Level 2	Activity Level 3
24	**PBM care for patients undergoing cardiac surgical or structural heart procedures.**	**X**	**N/A**	**N/A**

Entry #24 is new to the proposed edition and was added in recognition that these Standards reflect cardiac surgical settings. This will act as an activity level 1 requirement.

✎ **1.5.1 The program shall have a policies, processes and procedures to define and effectively address critical supplies, equipment and product inventory shortages.**

Standard 1.5.1 is new to the proposed edition and was based on language in the Standards for Blood Banks and Transfusion Services. This ensures that as a part of their operational continuity plan, all certified programs will have plans in place to address potential inventory shortages.

2.1.3.1 Corrective action shall be taken when competence has not been demonstrated.

The committee added new standard 2.1.3.1 to the proposed edition for completeness. This standard appears in other sets of AABB Standards and fills a gap.

2.1.4 Facility-Defined Educational Requirements

Individuals **involved in clinical PBM** ~~who order and/or transfuse blood~~ shall meet facility-defined requirements for education ~~related to PBM~~, **including evidence-based approaches to improving outcomes focused on patient centered care**.

The committee edited this standard to ensure that the facility defined education given to individuals was focused on patient blood management. The previous wording was deemed too broad.

3.0 Equipment

The program shall identify equipment critical to the activities defined in these *PBM Standards* and obtain documentation that this equipment has undergone and satisfied the required scheduled maintenance. The program shall have input in acquisition **decisions regarding** ~~of~~ equipment ~~needed~~ **necessary** to perform the activities defined in these *PBM Standards*.

The committee expanded the content of standard 3.0 for clarity, with the understanding that PBM programs are typically only a part of the decision making process when it comes to equipment and agreements.

3.1.3 The program shall have a process in place to minimize the risk and impact of an internal and external data breach.

The committee added new standard 3.1.3 to the proposed edition for completeness. This standard has been added to all other AABB Standards.

4. SUPPLIERS AND CUSTOMERS ~~ISSUES~~

4.0 Supplier<u>s</u> and Customer<u>s</u> ~~Issues~~

The program shall have policies, processes, and procedures to evaluate the ability of suppliers of components and services to ~~consistently~~ meet specified requirements.

The committee has replaced the title of chapter 4 and standard 4.0 to reflect similar changes made in every other set of Standards. The committee also removed the term "consistently" as it was deemed unnecessary.

4.2.2 Contract Services

The program shall ~~participate in the~~ review and evaluate agreements with suppliers responsible for providing any components or services critical to PBM. If **<u>a third-party provider performs the</u>** ~~any~~ PBM activities ~~are performed by a third party provider~~, the program shall be involved in the supplier qualification process.

The committee edited this standard for clarity, the intent of the content has not changed.

5.1 General Elements

5.1.1 The program shall have policies, processes, and procedures to ensure that:

<u>4) Patients with or at risk for coagulopathy are evaluated and managed.</u>

The committee added new number 4 to standard 5.1.1 for completeness. The committee wants to ensure that individuals with heavy bleeding potential are addressed in the Standards.

5.1.3 PBM Guidelines

The program shall **<u>utilize</u>** ~~establish~~ evidence-based ~~(when available)~~ PBM guidelines specific to the hospital's

inpatient and outpatient populations. These guidelines shall include practices to avoid **unnecessary** transfusion ~~when possible~~ and ensure early and rapid delivery of blood components to those who need them. These guidelines shall **include but are not limited to:**

1) managing anemia **and coagulopathy**, ~~through transfusion and other methods, including~~

2) minimizing blood loss **and promoting blood recovery**, ~~and autotransfusion of shed blood~~ and

3) managing asymptomatic anemia with medications as laboratory data support and according to activity level.

In addition, guidelines from major patient groups within the facility (service lines, care pathways) shall be reviewed to ensure **adherence to** ~~consideration of optimal~~ PBM **practices**.

The committee edited standard 5.1.3to include coagulopathy which is being added to standard 5.1.4 as well. The committee also added the promotion of blood recovery as a part of the guidelines reviewed by the program to meet the PBM Standards. The committee also created a list for readability in terms of what the guidelines must include at a minimum.

5.1.4.1 The program shall review all nonconformances, deviations from established procedures or protocol, and other incidents where **PBM** ~~transfusion~~ guidelines are not followed. Chapter 7, Deviations, Nonconformances and Adverse Events, and Chapter 9, Process Improvement Through Corrective and Preventive Action, apply.

The committee edited this standard for clarity, with a focus on PBM guidelines and not strictly transfusion.

5.1.5 Educational Materials

The program shall develop, **review** and distribute educational materials **at defined intervals** for hospital personnel and patients that:

1) Describe PBM ~~elements~~ **strategies** in the facility including, and as relevant to activity level, general PBM and any or all PBM in **surgical**, pediatric, obstetric, and outpatients.

4) Describe coagulopathy evaluation and management in surgical patients.

The committee edited standard 5.1.5 for completeness. Adding "defined intervals" to the standard ensures that educational materials are shared in program defined periods.
The addition of #4 is in line with the effort by the committee to continue to have standards focused on coagulopathy.

5.4.1 The program shall have policies for single-unit **component** transfusion strategies for defined **clinical settings** ~~patient populations~~.

The committee revised this standard for clarity. The addition of "component" was added to provide specifics. The term "clinical settings" replaced "patient populations" to align with similar changes to the standards.

5.5.3 The program shall implement transfusion guidelines and monitor adherence to these guidelines. Situations of over **or under** transfusion or failure to transfuse shall be identified and evaluated ~~and when indicated, root cause analysis shall be performed~~. **Standard 9.0 applies.**

The committee added the clause "or under" for completeness and removed the clause in strikethrough as it was deemed implied.

5.6.1 For elective procedural/surgical patients, the following shall be performed sufficiently in advance of the planned procedure to allow for successful treatment:

5) Consideration and plan for allogeneic blood needs and its alternatives, ~~including clinically indicated preoperative autologous blood donation, intraoperative blood recovery, hemostatic agents, acute normovolemic hemodilution, treating postoperative anemia with medications, and/or anemia tolerance~~.

The committee deleted the elements in subnumber 5 as it was deemed guidance where it will be moved to once published.

5.6.2 For **patients undergoing urgent or** emergent~~/urgent~~ **procedures**, there shall be processes and/or procedures for the following:

3) Assessment of patients' f**or pre-existing anemia and** physiologic ability to tolerate blood loss.

The committee edited this standard for clarity. The edits to the opening sentence was made for legibility.
Subnumber 3 has been edited to include an assessment of a patient's anemia. This is in line with changes made to the chart in chapter 1.

5.8 Postoperative or Postintervention Patient Care

The program shall ensure **monitoring of patients post-procedure** ~~that postoperative or postintervention patients are monitored~~ to determine the need for postoperative transfusion, or **other** anemia care, **including iron repletion**. The program shall oversee and review compliance with established PBM guidelines.

The committee edited this standard for clarity, the intent of the change to the

beginning of the standard has not changed the intent of the content.
The inclusion of "iron repletion" was done for completeness and is included as it a means of treating anemic patients.

5.11 PBM for Obstetric Patients

The program shall oversee and review policies, processes, and procedures for obstetric patients including:

1) Patients **who decline blood** ~~for whom blood is not an option~~.
3) **Antepartum and postpartum** ~~Prenatal~~ anemia management.

The committee edited subnumber 1 to remain in concert with similar changes made throughout the edition.
Subnumber 3 was edited for clarity and to expand where anemia management takes place, no longer prenatal, but for post partum as well.

5.11.1 Postpartum Hemorrhage Preparedness and Management

Postpartum hemorrhage preparedness and management shall identify:

1) Patients who decline blood.
3) Patients with known high bleeding risk (eg, placental **implantation** abnormalities).

Subnumber 1 is new to this edition and was added for completeness. This matches other changes and additions made to this edition.
The term "implantation" was added to subnumber 3 for accuracy.

5.17 Performance Indicators

The program shall obtain and review the following data at least quarterly (unless noted):

16) Bloodless Program enrollment / evaluation of effectiveness.

The committee created new subnumber 16 for completeness.

6.2.1.1 Copies

Before the destruction of the original records, the program shall have a process to ensure that copies of records are:
1) Verified as containing the original content,
2) Legible, **indelible,** complete, accessible, **and**
3) Identified as a copy

The committee edited this standard for legibility and to mirror the changes included in other sets of standards.

8.3 Reporting

The program shall report annually on its performance. The report shall include **but not limited to** the following~~, at a minimum~~, if required for the program's activity level:
6) Use of perioperative blood management techniques
10) **Adverse events associated with patient blood management activities** ~~Transfusion-associated adverse events and adverse events associated with the failure to transfuse.~~

The committee added subnumber 6 to remain in line with the requirements in the activity level chart in chapter 1.
Subnumber 10 has been edited to focus the requirements on PBM activities and moved away from transfusion. This change has been made elsewhere in the Standards.

1. ORGANIZATION

1.0 Organization

The patient blood management program (hereinafter referred to as the program) shall have a structure that clearly defines and documents the parties responsible for the oversight and review of patient blood management (PBM) activities and the relationship of individuals responsible for key quality functions. This interdisciplinary program shall be patient-centered, evidence-based, data-driven, and outcomes-focused.

1.1 Executive Management

The program shall have a defined executive management structure. Executive management shall have:

1) The responsibility and authority for oversight and review of the program.
2) The authority to establish or change the program's quality system.
3) The responsibility for compliance with these *PBM Standards* and applicable laws and regulations.
4) The responsibility for collecting and reviewing of data on PBM including patient outcomes and program performance metrics.
5) The responsibility to identify stakeholders and to communicate results to these stakeholders.

1.1.1 Medical Director Qualifications and Responsibilities

The program shall have a medical director who is a licensed provider / physician and qualified by education, training, and/or experience.

1.1.1.1 The medical director's responsibilities shall include, but not be limited to:

1) Leadership and oversight on clinical issues.
2) Consultative and support services on PBM matters that relate to the care and safety of patients.
3) Identification of program resources needed to conform to these *PBM Standards*.
4) Communication of program results and opportunities for improvement to executive management and hospital staff at least annually.

1.1.1.2 The medical director may delegate these responsibilities to another qualified individual(s); however, the medical director shall retain ultimate responsibility.

1.1.2 Executive management shall define the activities of the PBM program tied to patient outcomes.

1.1.2.1 A PBM program can be designated as a program activity level 1, 2, or 3 program. To be designated a specific activity level, the program shall be responsible for or have direct involvement with oversight and monitoring of the following activities:

Item	Responsibility	Activity Level 1	Activity Level 2	Activity Level 3
1	Evidence of institutional support for the PBM program at the hospital administration level.	X	X	X
2	Metrics regarding transfusion appropriateness consistent with transfusion guidelines.	X	X	X
3	Documentation of transfusion including patient consent, observation, adverse events, and outcomes.	X	X	X
4	Budgeting to the level of care required by implementing these *PBM Standards*.	X	X	X
5	Pretransfusion patient testing and evaluation.	X	X	X
6	Patient- or case-specific assessment of potential blood usage.	X	X	X
7	Pre-procedure blood ordering including completion of type and antibody testing before procedure start time with a plan for antibody-positive patients.	X	X	X
8	Pre-procedure assessment and management of patient coagulation status.	X	X	X

9	Monitoring of blood component wastage and cause.	X	X	X
10	Minimize blood loss due to laboratory testing (iatrogenic blood loss).	X	X	X
11	Process for managing the blood needs of unidentified patients and resolving their identification.	X	X	X
12	Processes to identify, before or upon admission, patients who may decline transfusion with notification to the appropriate individuals (including providers) and noted in the patient's medical record.	X	X	X
13	Massive transfusion protocol for all patient populations with documented evaluation of activation and protocol workflow effectiveness evidence of its use.	X	X	X
14	Transfusion care and anemia management of preterm, neonate, infant, and pediatric critical care patients, if applicable.	X	X	X
15	PBM care for obstetric patients including postpartum hemorrhage protocol with evidence of its use, plan(s) for patients with known high bleeding risk (eg, placental abnormalities), and plans for patients who decline blood.	X	X	X

16	Single-unit transfusion strategies for defined clinical settings.	X	X	X
17	Management of acquired coagulopathy.	X	X	X
18	Blood conservation strategies for service lines associated with high blood usage.	X	X	N/A
19	Processes and/or equipment to facilitate rapid decision-making concerning anemia and coagulation management.	X	X	N/A
20	Evaluating and managing iron and micronutrient deficiencies in patients with Red Blood Cells ordered in the inpatient and outpatient populations.	X	X	N/A
21	Evaluation and management of identified anemia in patients.	X	N/A	N/A
22	Program to care for patients who decline use of blood or blood-derived components.	X	N/A	N/A
23	Identification and management of presurgical anemia before elective procedures for patients at risk for red blood cell transfusion and/or adverse consequences of post-surgical anemia.	X	N/A	N/A
24	PBM care for patients undergoing cardiac surgical or structural heart procedures.	X	N/A	N/A

25	Use of perioperative techniques consistent with current AABB *Standards for Perioperative Autologous Blood Collection and Administration.*	X	N/A	N/A

1.1.3 Program Coordinator

The program shall have a program coordinator who is responsible for the operational aspects of the program.

1.1.4 Program Members

The program shall include representatives from administration, transfusion medicine, informatics, quality assurance, pharmacy, nursing, laboratory, and other departments that regularly transfuse, recommend, and/or have programmatic responsibility for the oversight of the transfusion of blood components and the management of anemic and bleeding patients.

1.2 Quality Plan

A patient-centered quality plan shall be defined, documented, implemented, and maintained to ensure reliability and reproducibility, and optimize patient outcomes. All program member representatives shall be aware of its content. The program medical director will review the quality plan biennially and when updates are made.

1.2.1 Scope

The quality plan shall encompass all the relevant policies, processes, procedures, protocols, and other work documents related to treating patients who may receive a blood transfusion, decline blood transfusion, or are managed per the activity level. Standard 1.1.2.1 applies.

1.2.2 Quality Representative

The quality plan shall be under the supervision of a designated person who reports to the medical director.

1.2.3 Executive Management Reviews

Executive management shall assess the effectiveness of the quality plan through scheduled reviews with the medical director.

1.3 Policies, Processes, and Procedures

Quality and operational policies, processes, and procedures shall be developed and implemented to ensure that these *PBM Standards* are satisfied and that patient outcomes are optimized. All such policies, processes, and procedures shall be in writing or captured electronically and shall be followed.

1.3.1 Any exceptions to policies, processes, and procedures warranted by clinical situations shall require justification and prior approval by the medical director or medical director designee on a case-by-case basis.

1.4 Disaster Preparedness

The program shall have emergency operation policies, processes, and procedures for all blood components to respond to the effects of internal, and external disasters, and massive casualty events. These emergency operation policies, processes, and procedures shall address all blood components.

1.4.1 The emergency management plan, including emergency communication systems, shall be tested at defined intervals.

1.5 Operational Continuity

Executive management shall ensure that the facility has policies, processes, and procedures that address continuity for potential events that put operations at risk.

1.5.1 The program shall have policies, processes and procedures to define and address critical supplies, equipment, and product inventory shortages.

1.6 Communication of Concerns

The program shall have a process for personnel to communicate concerns about quality or safety anonymously. Personnel shall be given the option to communicate such concerns either to their facility's executive management, AABB, or both. AABB's contact information shall be readily available to all personnel.

2. RESOURCES

2.0 Resources

The program shall have policies, processes, and procedures that ensure adequate resources to perform, verify, and manage all activities in the oversight and review of PBM.

2.1 Human Resources

The program shall have a process to ensure the employment and participation of individuals qualified by education, training, and/or experience. Current job descriptions shall be maintained and shall define appropriate qualifications for each position.

2.1.1 Qualification

Personnel performing critical tasks shall be qualified to perform assigned activities based on appropriate education, training, and/or experience.

2.1.2 Training

The program shall have a process for identifying training needs and shall provide training for personnel performing critical tasks.

2.1.3 Competence

Evaluations of competence shall be performed before independent performance of assigned activities and at specified intervals.

2.1.3.1 Corrective action shall be taken when competence has not been demonstrated.

2.1.4 Facility-Defined Educational Requirements

Individuals involved in clinical PBM shall meet facility-defined requirements for education, including evidence-based approaches to improving outcomes focused on patient centered care.

3. EQUIPMENT

3.0 Equipment

The program shall identify equipment critical to the activities defined in these *PBM Standards* and obtain documentation that this equipment has undergone and satisfied the required scheduled maintenance. The program shall have input in acquisition decisions regarding equipment necessary to perform the activities defined in these *PBM Standards*.

3.1 Information Systems

The program shall have processes to support the implementation and modification of software, hardware, and databases relating to these *PBM Standards*. These processes shall include:

1) Risk analysis, training, validation, implementation, and evaluation of post-implementation performance.
2) Information system maintenance and operation.
3) Documentation written in language understandable to the user.
4) Display and verification of data before final acceptance, when data are added, or when data are amended.
5) Evaluation, authorization, and documentation of modifications to the system.

3.1.1 Information Systems Records

Records of the following shall be maintained:

1) Validation of system software, hardware, databases, user-defined tables, electronic data transfer, and/or electronic data receipt.
2) Fulfillment of applicable life-cycle requirements for internally developed software.
3) Numerical designation of system versions, if applicable, with inclusive dates of use.

4) Monitoring of data integrity for critical data elements.

3.1.2 An alternative (backup) system shall be maintained to ensure continuous operation if computerized data and computer-assisted functions are unavailable. The alternative system shall be tested periodically. Processes and procedures shall address mitigation of the effects of disasters and include recovery plans.

3.1.3 The program shall have a process in place to minimize the risk and impact of an internal and external data breach.

3.2 Equipment Controlled by Other Departments

The program shall ensure the responsibility for control of equipment critical to PBM-related activities is defined.

3.2.1 Equipment controlled by the blood bank, transfusion service, clinical laboratory, or perioperative program shall be controlled in accordance with the manufacturer's written instructions and/or AABB *Standards for Blood Banks and Transfusion Services* and AABB *Standards for Perioperative Autologous Blood Collection and Administration.*

4. SUPPLIERS AND CUSTOMERS

4.0 Suppliers and Customers

The program shall have policies, processes, and procedures to evaluate the ability of suppliers of components and services to meet specified requirements.

✎ **4.1 Supplier Qualification**

The program shall evaluate and participate in selecting the of suppliers, when possible, before acceptance of an agreement.

4.1.1 When a supplier fails to meet specified requirements, it shall be reported to the management with the contracting authority.

4.1.2 Testing or services shall be performed in a facility accredited by AABB or an equivalent accrediting body.

✎ **4.2 Agreements**

Agreements, or changes to agreements, shall define supplier and customer expectations and shall reflect agreement.

✎ **4.2.1 Agreement Review**

Agreements and any incorporated changes shall be reviewed and communicated.

4.2.2 Contract Services

The program shall review and evaluate agreements with suppliers responsible for providing any components or services critical to PBM. If a third-party provider performs the PBM activities, the program shall be involved in the supplier qualification process.

5. PROCESS CONTROL

5.0 Process Control

The program shall have policies, processes, and procedures to ensure that patients who may need a transfusion are evaluated and managed in a manner to ensure that blood is or is not given when clinically appropriate. The program shall ensure that these policies, processes, and procedures are carried out consistently and under controlled conditions. These policies shall address anemia and transfusion-related care in emergent and non-emergent situations. These policies and procedures shall also address patients who decline blood transfusion. The program shall review, revise, or create the pretransfusion testing policies, processes, and procedures. These policies shall be consistent with the AABB *Standards for Blood Banks and Transfusion Services.* For the situation of emergent transfusion, policies shall define and ensure proper patient identification and the timely provision of blood.

5.1 General Elements

5.1.1 The program shall have policies, processes, and procedures to ensure that:

1) Patients who may need transfusion are evaluated and managed such that blood is given when clinically indicated.
2) Internal quality metrics for transfusion appropriateness are in place and reported.
3) Patients with anemia who may or may not need a transfusion are also assessed for other means by which it may be managed, including by minimizing bleeding and treating anemia with medications.
4) Patients with or at risk for coagulopathy are evaluated and managed.

5.1.2 Change Control

The program shall have a process to develop new processes or procedures or to change existing ones. This process shall include the identification of specifications and verification that specifications have been met. Before implementation, the new or changed processes or procedures shall be validated.

5.1.3 PBM Guidelines

The program shall utilize evidence-based PBM guidelines specific to the hospital's inpatient and outpatient populations. These guidelines shall include practices to avoid unnecessary transfusion and ensure early and rapid delivery of blood components to those who need them. These guidelines shall include but are not limited to:

1) managing anemia and coagulopathy,
2) minimizing blood loss and promoting blood recovery, and
3) managing asymptomatic anemia with medications as laboratory data support and according to activity level.

In addition, guidelines from major patient groups within the facility (service lines, care pathways) shall be reviewed to ensure adherence to PBM practices.

5.1.4 Monitoring

The program shall have a process for ongoing review of PBM practices.

5.1.4.1 The program shall review all nonconformances, deviations from established procedures or protocol, and other incidents where PBM guidelines are not followed. Chapter 7, Deviations, Nonconformances and Adverse Events, and Chapter

9, Process Improvement Through Corrective and Preventive Action, apply.

5.1.5 Educational Materials

The program shall develop, review and distribute educational materials at defined intervals for hospital personnel and patients that:

1) Describe PBM strategies in the facility including, and as relevant to activity level, general PBM and any or all PBM in surgical, pediatric, obstetric, and outpatients.
2) Describe anemia management in perioperative patients.
3) Describe anemia management in medical patients.
4) Describe coagulopathy evaluation and management in surgical patients.
5) Discuss the risks and benefits of transfusion of blood components and transfusion avoidance.
6) Review the alternatives to transfusion, including pharmacologic therapies.

5.1.6 Quality Control

A program of quality control shall be established that is sufficiently comprehensive to ensure that PBM-related equipment and methods function as expected. Results shall be reviewed and corrective action taken.

5.2 Phlebotomy

The program shall review, revise, or create policies, processes, and procedures that minimize blood volume collected for laboratory testing.

5.3 Consents, Approvals, and Notifications

The program shall participate in developing and revising of policies, processes, and procedures regarding patient consent for transfusion and the right to decline transfusion.

5.3.1 At a minimum, elements of consent shall include all of the following:

1) A description of the risks, benefits, and treatment alternatives.
2) The opportunity to ask and receive answers to the questions.
3) The right to accept or decline treatment.

5.3.2 For patients who decline blood or blood components, alternative blood loss minimization and anemia management strategies acceptable to the patient shall be documented in the medical record.

5.4 Transfusion Orders

Transfusion orders shall include an indication(s) for transfusion, as determined by program-defined guidelines.

5.4.1 The program shall have policies for single-unit component transfusion strategies for defined clinical settings.

5.5 Pre- and Posttransfusion Patient Care

The program shall have guidelines for patient care in the pre- and posttransfusion settings.

5.5.1 The program shall review, revise, or create the pretransfusion testing policies, processes, and procedures. These policies shall be consistent with the AABB *Standards for Blood Banks and Transfusion Services.*

5.5.2 The program shall create, review, and revise, as necessary, the policies, processes and procedures to measure transfusion effectiveness and appropriateness.

5.5.3 The program shall implement transfusion guidelines and monitor adherence to these guidelines. Situations of over or under transfusion or failure to transfuse shall be identified and evaluated. Standard 9.0 applies.

5.5.3.1 Data regarding adherence to these guidelines shall be reviewed quarterly and shared with the hospital administration and quality committees at least annually.

5.6 Preoperative or Preintervention Patient Care

The program shall oversee and review:

1) Maximum surgical blood ordering schedule (MSBOS) or equivalent and update as needed. The MSBOS shall be reviewed at a minimum biennially.
2) Procedures for identification of patients who decline transfusion.
3) Procedures for interventions to minimize the need for allogeneic transfusion.
4) The prescribing and ordering of appropriate blood components or transfusion-related pharmaceuticals (eg, factor concentrates, antifibrinolytics, hemostatic agents).

5.6.1 For elective procedural/surgical patients, the following shall be performed sufficiently in advance of the planned procedure to allow for successful treatment:

1) Evaluation and management of pre-procedure anemia.
2) Assurance of safe and effective discontinuation of anticoagulants and/or platelet inhibitors.
3) Assessment of bleeding risk.

4) Assessment of physiologic ability to tolerate anemia, iron deficiency, and coagulation systems stress.
5) Consideration and plan for allogeneic blood needs and its alternatives.

5.6.2 For patients undergoing urgent or emergent procedures, there shall be processes and/or procedures for the following:

1) Identification of unknown patients.
2) Assessment of bleeding risk.
3) Assessment of patient for pre-existing anemia and physiologic ability to tolerate blood loss.
4) Timely delivery of blood components.
5) Interventions to stop bleeding, including:
   a) directed interventions including hemostatic agents.
   b) protocols for rapid reversal of anticoagulants.
   c) assessment of recovering and reinfusing shed blood.

5.7 Methods for PBM During Surgery and Invasive Procedures

The program shall define and review methods for managing blood loss during surgery or invasive procedures.

5.8 Postoperative or Postintervention Patient Care

The program shall ensure monitoring of patients post-procedure to determine the need for postoperative transfusion, or other anemia care, including iron repletion. The program shall oversee and review compliance with established PBM guidelines.

5.9 Patients Who Do Not Require Invasive Procedures

The program shall oversee and review:

1) Procedures for identification of patients who decline transfusion.
2) Procedures for identifying patients who may benefit from medications or treatments to minimize the need for allogeneic transfusion.
3) The prescribing and ordering of blood components or alternatives to transfusion.

5.10 Anemia Care Inpatients

Based on activity level, the program shall have policies, processes, and procedures in place to manage anemia in nonsurgical inpatients, including patients suffering from iron and/or micronutrient deficiency.

5.11 PBM for Obstetric Patients

The program shall oversee and review policies, processes, and procedures for obstetric patients including:

1) Patients who decline blood.
2) Identification and management of pregnancies with known risk for hemolytic disease of the fetus and newborn or neonatal alloimmune thrombocytopenia.
3) Antepartum and postpartum anemia management.

5.11.1 Postpartum Hemorrhage Preparedness and Management

Postpartum hemorrhage preparedness and management shall identify:

1) Patients who decline blood.
2) Quantitative cumulative assessment of maternal blood loss for all patients.
3) Patients with known high bleeding risk (eg, placental implantation abnormalities).
4) Postpartum hemorrhage protocol including predelivery risk assessment, postdelivery patient identification with a stepwise process to manage

bleeding, massive transfusion protocol, and/or patient transfer.

5.12 Massive Blood Loss and Emergent Care

The program shall have policies, processes, and procedures for the timely delivery of blood and blood components to manage patients experiencing massive bleeding and patients in other emergent situations.

5.12.1 The program shall ensure compliance with the processes and procedures for the managing and delivering blood and blood components for patients with emergency blood requirements, including massive blood loss.

5.13 Reversal of Acquired Coagulopathy

The program shall have a plan in place to rapidly reverse acquired coagulopathy. This plan shall include the dispensing of medications and/or blood and blood components as clinically indicated. The program shall monitor the plan at defined intervals.

5.14 PBM for Pediatric Patients

The program shall establish guidelines and plans for the care of preterm and term neonates, infants, and children.

5.15 PBM for Outpatients

The program shall oversee and review policies or processes to ensure that iron and/or micronutrient deficiency is considered, evaluated, and corrected in patients with Red Blood Cell orders in the outpatient setting.

5.16 High Blood Use Service Lines

The program shall oversee and review policies, procedures, and plans by high blood loss service lines to ensure strategies are in place to manage blood loss and treat anemia.

5.17 Performance Indicators

The program shall obtain and review the following data at least quarterly (unless noted):

1) Blood and blood component use.
2) Blood and blood component use appropriateness.
3) Blood administration policy compliance.
4) Blood and blood component wastage and discard, including reasons for unused components.
5) Crossmatch-to-transfusion ratio.
6) Deviation from transfusion service procedures or protocols.
7) Transfusion reactions by category.
8) Informed consent for blood transfusion.
9) Massive transfusion protocol use.
10) Single-unit RBC transfusion practice performance metric.
11) Use of intraoperative blood recovery equipment and quality control.
12) Anemia program utilization.
13) Iron and micronutrient deficiency identification and management in the outpatient transfusion setting.
14) Blood infusion equipment and warmer(s) maintenance program (annually).
15) External assessment results (eg, AABB or equivalent accrediting body) (biennially).
16) Bloodless Program enrollment / evaluation of effectiveness.

Standard 8.4 applies.

6. DOCUMENTS AND RECORDS

6.0 Documents and Records

The program shall have policies, processes, and procedures to ensure that documents are identified, reviewed, approved, and retained and that records are created, stored, and archived in accordance with record retention policies. In addition, documents and records related to transfusion medicine or perioperative programs records shall be created and controlled in accordance with the AABB *Standards for Blood Banks and Transfusion Services* and AABB *Standards for Perioperative Autologous Blood Collection and Administration* or the requirements of an equivalent accrediting body.

6.1 Documents

The program shall have a process for document control that includes the following elements:

6.1.1 A master list of documents, including policies, processes, procedures, labels, and forms related to these *PBM Standards.*

6.1.2 Use of standardized formats for all policies, processes, procedures, and forms. Additional procedures (such as those in an operator's manual) may be incorporated by reference.

6.1.3 Review and approval of new and revised documents before use.

6.1.4 Review of each policy, process, and procedure by an authorized individual at a minimum every 2 years.

6.1.5 Use of only current and valid documents. Documents shall be available at all locations where activities essential to meeting these *PBM Standards* are performed.

6.1.6 Identification and archival of obsolete documents.

6.1.7 Storage in a manner that preserves legibility and protects from accidental or unauthorized access, destruction, or modification.

6.2 Records

The program shall ensure identification, collection, indexing, access, filing, storage, and disposition of records (including electronic records) as required by the facility.

6.2.1 Facility Records

Records shall be complete, retrievable in a period appropriate to the circumstances, and protected from accidental or unauthorized destruction or modification.

6.2.1.1 Copies

Before the destruction of the original records, the program shall have a process to ensure that copies of records are:

1) Verified as containing the original content,
2) Legible, indelible, complete, accessible, and
3) Identified as a copy

6.2.2 A system designed to prevent unauthorized access and ensure confidentiality of records shall be established and followed. This system shall ensure compliance with Health Insurance Portability and Accountability Act (HIPAA) regulations.

6.2.2.1 The program shall have access to patient records. Information in the record system shall allow the program to trace any patient from the preoperative/pretransfusion period to the postoperative/posttransfusion period, and the care and blood management services provided to the patient. In addition, the record system shall allow the evaluation of outcomes of specific interventions associated with blood management, and investigate adverse events.

6.2.3 Electronic Records

There shall be processes and procedures to support the management of information systems.

6.2.3.1 There shall be a process in place for routine backup of all critical data.

6.2.3.1.1 Procedures shall be in place to ensure that data are retrievable and usable.

6.2.3.1.2 Backup data shall be stored in an off-site location.

6.2.3.2 There shall be a process in place for linking patient records to those contained in the laboratory information system.

6.3 Policies, Processes, and Procedures Controlled by Other Departments

The program shall develop new policies and changes to existing policies, processes, and procedures that affect the quality of the program's activities, even when another department controls these documents.

6.3.1 The program shall ensure that responsibility for revision and changes to policies, processes, and procedures that affect the quality of the program's activities is defined. Standard 5.1.2 applies.

Reference Standard 6.2A—Retention of Records

Item No.	Standard	Record to Be Maintained	Minimum Retention Time (in years)
1	1.1.1.2	Delegation of medical director responsibilities to another qualified individual(s)	5
2	1.2.3	Management review of the effectiveness of the quality system	5
3	1.4.1	Emergency management plan review	5
4	2.1	Job descriptions	5
5	2.1.1	Qualification of personnel performing activities affecting quality	5
6	2.1.2	Evaluations of competence	5
7	2.1.3	Personnel records of PBM program employees	5
8	2.1.4	Facility-defined educational requirements for individuals who order and/or transfuse blood	5
9	3.1	Implementation of new or modified software, hardware, or databases and modifications of existing software, hardware, or databases	2 years after retirement of the system

10	3.1.1	1) Validation of system software, hardware, databases, and user-defined tables 2) Fulfillment of applicable life-cycle requirements 3) Numerical designation of system versions, if applicable, with inclusive dates of use 4) Monitoring of data integrity for critical data elements	2 years after retirement of the system
11	4.1	Evaluation and participation in selection of suppliers of products and PBM-related services	5
12	4.2	Agreements	5
13	4.2.1	Review of agreements	5
14	5.1.2	Validation of new or changed processes and procedures	5
15	5.1.4	Review of blood management and utilization practices	5
16	5.1.5	Blood management educational materials	5
17	5.1.6	Review of quality control results for PBM-related equipment and methods	5
18	5.3	Patient consent	5
19	5.3.2	Alternative strategies acceptable to patients who decline blood	5

20	6.1.3	Review and approval of new and revised documents before use	5
21	6.1.4	Biennial review of policies, processes, and procedures	5
22	6.1.6	Identification and appropriate archival of obsolete documents	5
23	7.0, 7.1	Description and evaluation of nonconformances	5
24	8.2.2	Reviews of results of internal and external assessments and associated corrective and preventive action	5
25	9.0	Implementation of changes to policies, processes, and procedures resulting from corrective and preventive action	5
26	9.2	Corrective action	5
27	9.3	Preventive action	5

7. DEVIATIONS, NONCONFORMANCES, AND ADVERSE EVENTS

7.0 Deviations, Nonconformances, and Adverse Events

The program shall have policies, processes, and procedures to capture, assess, investigate, and monitor deviations from meeting, or failing to meet, specified requirements. The investigation shall, when applicable, include an assessment of the effect of policy deviations on patient safety. The responsibility for review and authority for the disposition of nonconforming blood, blood components, perioperative products, critical materials, and services shall be defined. Deviations, nonconformances, and adverse events shall be reported in accordance with specified requirements and to outside agencies as required. The program shall ensure that all deviations, nonconformances, and adverse events related to blood transfusion are managed in accordance with the AABB *Standards for Blood Banks and Transfusion Services* and AABB *Standards for Perioperative Autologous Blood Collection and Administration* or the requirements of an equivalent accrediting body.

7.1 Nonconformances

Upon discovery, nonconformances shall be evaluated and their disposition determined. Chapter 9, Process Improvement Through Corrective and Preventive Action, applies.

7.1.1 The program shall have a process for capturing the nonconformances related to these *PBM Standards.*

8. ASSESSMENTS: INTERNAL AND EXTERNAL

8.0 Assessments: Internal and External

The program shall have policies, processes, and procedures to ensure that internal and external assessments of operations and quality systems are scheduled and conducted.

8.1 Review Process

The program shall collect, tabulate, and analyze data at defined intervals and determine the number and type of nonconformances.

8.2 Management of Assessment Results

The results of internal and external assessments shall be provided to and reviewed by personnel responsible for the area being assessed.

8.2.1 When corrective action is taken, it shall be developed, implemented, and evaluated in accordance with Chapter 9, Process Improvement Through Corrective and Preventive Action.

8.2.2 The results of internal and external assessments and associated corrective and preventive actions shall be reviewed by the program's executive management.

8.3 Reporting

The program shall report annually on its performance. The report shall include but not limited to the following if required for the program's activity level:

1) Overall program effectiveness and opportunities for improvement.
2) Allogeneic transfusion rates overall and by program-defined high blood use groups.

3) Appropriateness of allogeneic transfusion overall and by program-defined high blood use groups.
4) Blood and blood component discard and cause(s) of waste.
5) Use and efficacy of preoperative anemia management interventions.
6) Use of perioperative blood management techniques
7) Effectiveness of nonoperative anemia management.
8) Use and effectiveness of the emergency/massive transfusion processes and protocols.
9) Compliance with recommendations made by the program.
10) Adverse events associated with patient blood management activities.
11) Program financial impact.
12) Program performance goals and other needs for next reporting period.

8.4 Quality Monitoring

The program shall have a process to collect and evaluate quality indicator data on a scheduled basis.

9. PROCESS IMPROVEMENT THROUGH CORRECTIVE AND PREVENTIVE ACTION

9.0 Process Improvement Through Corrective and Preventive Action

The program shall have policies, processes, and procedures for data collection, analysis, and follow-up of issues requiring corrective and preventive action, including near-miss events.

9.1 Data Collection

The program shall provide all data generated from the utilization review process to the program members for review and analysis.

9.1.1 These data shall be analyzed for trends across the institution and within specific departments or services.

9.2 Corrective Action

The program shall have a process for corrective action of deviations, nonconformances, and complaints relating to blood, blood components, perioperative products, critical materials, and services, which includes the following elements:

1) Description of the event.
2) Investigation of the cause.
3) Determination of the corrective action(s).
4) Implementation of the corrective action(s).
5) Evaluation to ensure that corrective action is taken and is effective.

9.2.1 As an element of corrective action, the program shall monitor:

1) A provider's ordering practices.
2) Use of transfusion and/or alternatives.
3) Effectiveness of transfusions and/or alternatives.

4) Adverse events, including suspected transfusion reactions and other patient complications.

9.2.1.1 These findings shall be reported to the provider(s) by the program's medical director.

9.3 Preventive Action

The program shall have a process for preventive action that includes the following elements:

9.3.1 Review of information including assessment results and complaints to detect and analyze potential causes of nonconformances.

9.3.2 Determination of steps needed to respond to potential problems requiring preventive action.

9.3.3 Initiation of preventive action and application of controls to monitor effectiveness.

10. FACILITIES AND SAFETY

10.0 Facilities and Safety

The program shall adhere to the facility's policies, processes, and procedures to provide safe environmental conditions. Where applicable, safety programs shall meet local, and federal regulations.

GLOSSARY

Acute Normovolemic Hemodilution: The short-term removal of whole blood (usually immediately before surgery) into a standard blood bag containing anticoagulant with the simultaneous replacement of intravascular volume using acellular fluids. The product is reinfused to the patient during the perioperative period. It does not include the hemodilution that occurs due to extracorporeal circulation, or fluid replacement. Acute normovolemic hemodilution for the purposes of these *PBM Standards* would not include autologous blood donation.

Adverse Event: A complication related to patient blood management activities.

Agreement: A contract, order, or understanding between two or more parties, such as between a facility and one of its customers.

Agreement Review: Systematic activities to ensure that requirements are adequately defined, free from ambiguity, documented, and achievable.

Anemia: A condition in which the body does not have enough healthy red cells. Red cells provide oxygen to body tissues.

Assessment: A systematic examination to determine whether actual activities comply with planned activities, are implemented effectively, and achieve objectives. Assessments usually include a comparison of actual results with expected results. Types of assessments include external assessments, internal assessments, peer review, and self-assessments.

Autologous: Concerning blood, involving a specific person as both the donor and the recipient.

Calibrate: To set measurement equipment against a known standard.

Competence: The ability of a person to perform a specific task according to procedures.

Competent Authority: The agency(ies) responsible under its local or national law for regulations.

Compliance: See Conformance.

Conformance: Fulfillment of requirements. Requirements may be defined by customers, practice standards, regulatory agencies, or the law.

Corrective Action: An activity performed to eliminate the cause of an existing nonconformance or other undesirable situation and to prevent a recurrence.

Critical Equipment/Materials/Tasks: A piece of equipment, material, service, or task that can affect the quality of the facility's products or services.

Customer: The receiver of a product or service. A customer may be internal (ie, another department within the same organization) or external (ie, another organization).

Damage Control Procedures: Preserving physiology at the expense of normal anatomy including but not limited to packing, shunts, tractotomy, bowel stapling.

Deviation(s): A departure from policies, processes, procedures, applicable regulations, standards, or specifications.

Disaster: An event (internal, local, or national) that can affect the activities of the PBM program or the safety of staff and patients.

Document *(noun)*: Written or electronically generated information and work instructions. Examples of documents include quality manuals, procedures, or forms.

Document *(verb)*: To capture information through writing or electronic media.

Equipment: A durable item, instrument, or device used in a process or procedure.

Establish: To define, document, and implement.

Executive Management: The highest level of personnel within an organization, including employees and independent contractors, who have responsibility for the organization's operations and who have the authority to establish or change the organization's quality policy. Executive management may be an individual or a group of individuals.

Facility: A location or operational area within an organization. The part of the organization that is assessed by the AABB and receives AABB accreditation for its specific activities.

Inspect: To measure, examine, or test one or more characteristics of a product or service and to compare the results with specific requirements.

Intraoperative: During a surgical procedure.

Label: An inscription affixed to a product for identification.

Maintain: To keep in the current state.

Material: A good or supply item used to prepare the final product or service in a process or procedure.

Maximum Surgical Blood Ordering Schedule: An institution-specific listing of surgical procedures with the standard preoperative blood order for each procedure (ie, no blood order, type and screen, or type and crossmatch for a certain number of units) to optimize the availability of blood components for patients during the surgical procedure while limiting excessive ordering and wastage.

Near-miss event: An unexpected occurrence that did not adversely affect the outcome, but could have resulted in a serious adverse event.

Neonate: A child less than 4 months of age.

Nonconformance: Failure to meet requirements.

Organization: An institution, or part thereof, that has its functions and executive management.

Perioperative: During the time around a surgical procedure. For these *PBM Standards*, the perioperative period typically includes the day of surgery and the first day after surgery.

Perioperative Product: Whole blood, blood components, recovered blood, or blood component concentrates collected or administered during the perioperative period.

PBM Program: A program within an organization that provides the services outlined in these *PBM Standards*.

Policy: A documented general principle that guides present and future decisions.

Postoperative: After a surgical procedure.

Preterm Neonate: A premature infant born before 37 completed weeks of gestation.

Preoperative: Before a surgical procedure.

Preventive Action: An action taken to reduce the potential for nonconformance or other undesirable situation.

Procedure: A series of tasks usually performed by one person according to instructions.

Process: A set of related tasks and activities that accomplish a work goal.

Process Control: Efforts to standardize and direct processes to produce predictable output.

Product: A tangible result of a process or procedure.

Qualification: For individuals, the aspects of an individual's education, training, and experience are necessary to meet the requirements of the position successfully. For equipment, verification that specified attributes required to accomplish the desired task have been met.

Quality: Characteristics of a product or service that bear on its ability to meet requirements, including those defined during the agreement review.

Quality Control: Testing routinely performed on materials and equipment to ensure their proper function.

Quality Indicator Data: Information collected and used to determine whether an organization is meeting its quality objectives as defined by

executive management in its quality policy. Indicators are measured by data for movement or regression concerning those quality intentions. The data used for monitoring a quality indicator may consist of single-source data or multiple-source data, as long as it is clear how the data will come together to define the indicator.

Quality System: The organizational structure, responsibilities, policies, processes, procedures, and resources established by executive management to achieve quality.

Record (*noun*): Information captured in writing or through an electronically generated medium that provides objective evidence of activities that have been performed or results that have been achieved, such as test records or audit results. Records do not exist until the activity has been performed and documented.

Record *(verb)*: To capture information for records through writing or electronic media.

Regulations: Rules promulgated by federal or local authorities to implement laws enacted by legislative bodies.

Service: An intangible result of a process or procedure.

Shall: A verb used to indicate a requirement.

Specified Requirements: Any requirements in these *PBM Standards* and including but not limited to FDA or Competent Authority requirements; requirements of a facility's internal policies, processes, and procedures; manufacturers' instructions; customer agreements; practice standards; and requirements of accrediting organizations such as the AABB.

Supplier: An entity that provides an input product or service.

Supplier Qualification: An evaluation method designed to ensure that input materials and services (eg, materials, blood components, and patient blood samples) obtained from a supplier meet specified requirements.

System: A subgroup of related activities performed by a particular organization. Activities dealing with maintaining product and service quality are organized into a quality system.

Third-Party : An entity that contracts with a hospital or other medical facility to provide on-site PBM services.

Traceability: The ability to follow the history of a product or service using recorded identification.

User-Defined Tables: Data maintained in tables and used by computer programs to direct their operations. Typically, user-defined tables contain data unique to a specific installation, and thus they may change from system to system.

Validation: Establishing recorded evidence that provides a high degree of assurance that a specific process will consistently produce an outcome meeting its predetermined specifications and quality attributes.

Verification: Confirmation by examination and provision of objective evidence that specified requirements have been met.