PREFACE

The Standards Program Committee (SPC) and the Patient Blood Management Standards Committee (PBM SC) are pleased to present this 5th edition of *Standards for a Patient Blood Management Program (PBM Standards).*

The SPC is the umbrella committee whose primary role is to oversee the creation, development, and revision of all AABB standards to ensure harmonization and consistency in AABB's standard-setting activities. The SPC consists of a committee chair, the chair of the Standards Subcommittee for the Evaluation of International Variances, and the chairs of the 10 standards committees.

The PBM SC developed this 5th edition of *PBM Standards* using an evidence-based decision-making process, when possible, to modify existing requirements or to create new ones.

The PBM SC consists of the chair and committee members recognized as leaders in patient blood management (PBM). The *PBM Standards* was developed and modified based on input from a variety of sources, including AABB members, the public, and recognized experts in PBM.

Although the *PBM Standards* provides a great amount of information concerning the PBM arena, other AABB resources may provide even more specific recommendations. When using this edition of the *PBM Standards*, readers may find that having access to the current editions of the AABB *Technical Manual,* the *Standards for Blood Banks and Transfusion Services*, and the *Standards for Perioperative Autologous Blood Collection and Administration* could be of service in understanding and implementing these requirements.

The PBM SC has published a document providing informal responses to the comments received during the comment period, explaining why the PBM SC adopted a suggestion or did not. This document can be found on the AABB website at the following address: http://www.aabb.org/sa/standards/Pages/library.aspx.

This 5th edition of *PBM Standards* implements AABB's updated quality system essentials. The quality system essentials were first introduced by

AABB in Association Bulletin #97-04 and have served as the framework on which the *PBM Standards* have been presented since 2016. Since 2016, the quality requirements in the **PBM Standards** (and all sets of AABB *Standards*) have been updated on an as-needed basis, with changes occurring incrementally but not in a universally applicable fashion. This updated version of the quality system essentials has been standardized in terms of language and style and incorporated in all sets of AABB *Standards* as they are updated, beginning with the 16th edition of *Standards for Relationship Testing Laboratories*, effective January 1, 2024. The updated quality system essentials include the following updates:

- All standards are written in the active voice.
- Once a requirement has been stated, it is not repeated.
- Each chapter begins with a description of what the standards therein cover.
- Each chapter contains a list of key terms that relate to the content of the chapter, with their definitions.
- Each chapter contains a list of examples of objective evidence that an assessor could look for during an on-site assessment; however, this list is not comprehensive, nor will it be assessed against by an assessor. It is merely for guidance purposes only.
- Each chapter now concludes with the record retention table for that chapter. Note that a comprehensive record retention table still exists at the end of Chapter 6.

The AABB and the PBM SC feel that these updates across these *PBM Standards* (and all *Standards*) will provide a reset and upgrade on the previous version of the quality system essentials and will allow these *PBM Standards* to take the next step in quality.

The 5th edition of the AABB *PBM Standards* underscores the committee's dedication to advancing the global definition of PBM, emphasizing that PBM is a comprehensive approach to "blood health" that extends beyond optimal transfusion practices. The committee's mission is to establish minimum standards for PBM that are measurable and contribute to improved patient outcomes. Achieving this goal requires a collaborative effort, drawing on the expertise of individuals with diverse backgrounds and experiences.

Within the committee, we foster a supportive environment that encourages the exchange of innovative ideas and even dissenting viewpoints. This collaborative space facilitates enriching discussions that drive the development of these standards. I extend my heartfelt commendation to the committee members for their invaluable volunteer contributions, time, and thoughtful participation. Gratitude also goes to AABB for recognizing the importance of PBM and for the ongoing support in shaping its future.

Deborah J. Tolich, DNP, MSN, RN
Chair, Patient Blood Management Standards Committee

INTRODUCTION

The *Standards for a Patient Blood Management Program (PBM Standards)* was prepared by the Patient Blood Management Standards Committee (PBM SC) and the Standards Program Committee (SPC) of the AABB. The goal of the *PBM Standards* is to maintain and enhance the quality and safety of care for patients who may or may not require transfusion. The following frequently asked questions will help users of this publication better understand this 5th edition of *PBM Standards.*

What activities are covered by the *PBM Standards*?
For the purposes of this publication, a patient blood management program encompasses all aspects of patient evaluation and clinical management surrounding the transfusion decision-making process, including the application of appropriate indications, as well as minimization of blood loss and optimization of patient red cell mass.

When does this edition go into effect?
The effective date of this edition is June 1, 2025.

Are the standards requirements or recommendations?
The *PBM Standards* contains requirements. A requirement contains the word "shall," which indicates that the statement is mandatory. There are rare instances in which an AABB standard uses the term "may." A statement that uses "may" is not a requirement.

How does this publication relate to laws and regulations?
The *PBM Standards* was developed on the basis of good medical practice and, when available, scientific and evidence-based data. The requirements in this publication can be followed by a patient blood management program located anywhere in the world, but they do not preempt any federal, state, and/or local laws and regulations. Although the majority of the standards here are intended to be consistent with these applicable

laws and requirements, no assurances can be given that compliance with *PBM Standards* will result in compliance with all applicable laws and requirements. The *PBM Standards* are not intended as a substitute for legal advice, and the content should not be relied upon for legal purposes. Therefore, users must make their own determinations as to how best to ensure compliance with all applicable laws and requirements, including consultation with legal counsel familiar with these issues.

Does this publication require me to follow my own local laws and regulations?

Yes. In many standards, the PBM SC chose to use the term "specified requirements." This phrase is defined in the glossary to include any applicable requirement under which a program might operate. These requirements could include, but are not limited to, federal regulations, customer agreements, practice standards, instructions for the intended use of a device, or requirements of an accrediting organization.

What is meant by "program activity levels"?

The *PBM Standards* recognizes that differences exist among hospitals concerning the range of clinical services offered. As a result, the PBM SC created three program activity levels (Levels 1, 2, and 3) based on the functions provided at an individual facility. For example, a small hospital may have a clinical program and services that meet the program level activities described as Level 3. Likewise, a large hospital might incorporate all the activities that are described as Level 1. It should be recognized that one level is not superior to another, and merely reflects differences in activities performed by the hospital in which the program resides.

What does the pen symbol (✎) mean?

When the pen symbol precedes a standard, users have to maintain a record of that activity in order to meet the standard. Readers should refer to the record retention tables at the end of each chapter and the comprehensive reference standard at the end of Chapter 6 to determine what that record must contain, as well as the required record retention time.

What other tools are available to help me implement the *PBM Standards*?

There are several other resources to assist users. This publication also includes:

- A glossary, which reflects the usage of specific words or phrases in the context of these *PBM Standards.*
- A crosswalk that cross-references the standards in this edition of *PBM Standards* with those in the previous edition.

In addition, users of this edition may want to:

- Visit the AABB website for a document that details the significant changes to this edition. This document is titled "Significant Changes and Response to Comments" to the 5th edition.
- Follow guidance to the 5th edition of *PBM Standards*, found in the AABB Standards Portal online or as a printed stand-alone copy of the published *Guidance for Standards for a Patient Blood Management Program*. The guidance provides rationales behind significant changes to this edition of *PBM Standards* and provides recommendations on how to meet the intent of certain standards.
- Contact the Standards Department (standards@aabb.org) to ask for interpretations or to submit a variance request. Variances to standards are effective for the edition of *PBM Standards* for which they are received. Request forms for variances can be found on the AABB website. Requests for renewal of previously granted variance requests must be submitted prior to the effective date.