PREFACE

he Standards Program Committee (SPC) and the Patient Blood Management Standards Committee (PBM SC) are pleased to present this 3rd edition of *Standards for a Patient Blood Management Program*.

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, as well as the chairs of the eight specialty program units.

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

Although the *PBM Standards* provides a great amount of information concerning the patient blood management 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.

As I write these words, in March 2020, we are 3 months into the COVID-19 pandemic. Originally, I had considered the next phase of patient blood management expansion to be managing anemia, especially in obstetric and pediatric patients. However, we are entering a new PBM

phase, which is managing patients' blood needs in a time of scarce resources and uncertainty.

Heartfelt thanks go to my esteemed colleagues on the committee for their work in significantly updating this edition. The guidance document is also fairly robust, containing considerably more information on how the programmatic components may be provided as well as helpful references.

And thank you to all of you—PBM practitioners. Our previous work in PBM and the significant content updates in this edition ensure that we are up to the task that world circumstances have delivered to us. No doubt by the time the next edition is released, we will have learned many new things.

Kathrine Frey, MD Chair, Patient Blood Management Standards Committee

INTRODUCTION

he *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 3rd 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 January 1, 2021.

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 is 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 (Level 1, 2, and 3) based upon 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 a Level 1. It should be recognized to the control of the co nized 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 must maintain a record of that activity in order to meet the standard. Readers should refer to Reference Standard 6.2A at the end of Chapter 6 to determine what that record must contain.

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 also want to:

- Visit www.aabb.org for a document that details the disposition and resolution of all comments received to this edition. This document is entitled, "Response to Public Comments" to this 3rd edition. When a public comment is the source of a change, or where the PBM SC did not make a change suggested by a comment, an explanation is provided.
- Follow guidance to the 3rd edition of *PBM Standards*, found in the printed publication or online in the electronic version of the 3rd edition in the Standards Portal (standards.aabb.org). 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 standards@aabb.org 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 at http://www.aabb.org.