#### **PREFACE**

he Standards Program Committee (SPC) and the Prehospital and Out-of-Hospital Standards Committee are pleased to present this 1st edition of Standards for Emergency Prehospital and Scheduled Out-of-Hospital Transfusions (Prehospital and Out-of-Hospital 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 Prehospital and Out-of-Hospital Standards Committee developed this 1st edition of *Prehospital and Out-of-Hospital Standards* using an evidence-based decision-making process, when possible, to modify existing requirements or to create new ones.

The process of developing the requirements in *Prehospital and Out*of-Hospital Standards requires that the final publication reflect the concerns and priorities of several different aspects of the discipline, including the input of recognized experts in the field and the best interests of patients. In addition, the Prehospital and Out-of-Hospital Standards was developed in the context of the global drive for quality in health care and internationally recognized principles of quality management. To this end, the Prehospital and Out-of-Hospital Standards Committee also consulted the scientific literature on out-of-hospital transfusion and prehospital techniques to ensure that the Prehospital and Out-of-Hospital Standards reflects current strategies for ensuring patient safety. Accordingly, the Prehospital and Out-of-Hospital Standards is based on input from a variety of sources, including member and public comments. In an effort to harmonize AABB publications, all Standards have incorporated the AABB's recently updated quality system essentials as the foundation of the Standards. A facility will be assessed only on activities it performs.

The *Prehospital and Out-of-Hospital Standards* contains requirements that must be implemented by AABB-accredited programs. Requirements are statements, signified by the use of the term "shall." *Guidance for Standards for Emergency Prehospital and Scheduled Out-of-Hospital Transfusions*, 1st edition, could be of assistance in understanding and implementing these requirements, but a program will be assessed only upon the standards. Guidance for specific standards that appear in this edition of the *Prehospital and Out-of-Hospital Standards* is published in the Standards Portal and in printed form. Guidance entries are crafted from the committee, member clarification requests, and approved variances.

As mentioned, this 1st edition of *Prehospital and Out-of-Hospital 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 for all sets of AABB *Standards* published since that date. Since the implementation of the quality system essentials, the quality requirements in all sets of AABB *Standards* had been updated on an as-needed basis, with changes occurring incrementally but not in a universally applicable fashion.

In 2023, AABB updated the quality system essentials, which have been standardized in terms of language and style. This version is being incorporated in all sets of AABB *Standards* beginning with the 16th edition of *Standards for Relationship Testing Laboratories,* which was 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 Prehospital and Out-of-Hospital Standards Committee feel that these updates across these *Prehospital and Out-of-Hospital Standards* (and all *Standards*) will provide a reset and upgrade on the previous version of the quality system essentials and will allow these *Prehospital and Out-of-Hospital Standards* to take the next step in quality.

The Prehospital and Out-of-Hospital Standards Committee has published a document providing informal responses to the comments received during the comment period, explaining why the committee adopted a suggestion or did not. This document can be found on the AABB website (https://www.aabb.org/standards-accreditation/standards/about-aabb-standards/standards-library).

As we release this inaugural edition of the *Prehospital and Out-of-Hospital Standards*, I am deeply proud of the effort displayed by this committee and our partners in the transfusion medicine community. AABB's engagement with members over the past few years has underscored an essential truth: collaboration and commitment can have a profound impact on patient care and outcomes. This edition symbolizes the development of standards designed to meet the unique challenges and demands of the prehospital and out-of-hospital settings.

Bringing this vision to life required an exceptional degree of dedication and expertise from all involved. The committee's work reflects our commitment to patient safety and acknowledges the evolving land-scape for blood administration. I want to express my heartfelt gratitude to each member of the committee for their insights, rigor, and passion for advancing transfusion medicine practices.

I also wish to extend my deepest gratitude to AABB for entrusting us with this awesome responsibility. Your confidence in our ability to undertake and complete this important work has been both an honor and a source of motivation for us all. This first edition is more than a guideline; it is a response to the needs of our field and a commitment to uphold the highest levels of care for patients in some of the most critical moments. It is my hope that these standards will serve as a

meaningful resource for the field, supporting the delivery of lifesaving care in prehospital and out-of-hospital environments.

Thank you to everyone who contributed to this vital initiative. I look forward to the positive impact these standards will have on prehospital and out-of-hospital transfusion services worldwide.

Audra L. Taylor, MS, SBB(ASCP) Chair, Prehospital and Out-of-Hospital Standards Committee

#### INTRODUCTION

he Standards for Emergency Prehospital and Scheduled Outof-Hospital Transfusions (Prehospital and Out-of-Hospital Standards) was prepared by the Prehospital and Out-of-Hospital Standards Committee and the Standards Program Committee of the AABB. The goal of the Prehospital and Out-of-Hospital Standards is to maintain and enhance the quality and safety of prehospital and out-of-hospital transfusions and to provide a basis for the Accreditation Program of the AABB.

The following frequently asked questions will help users of this publication better understand the 1st edition of *Prehospital and Out-of-Hospital Standards:* 

### When does this edition go into effect?

The effective date of this edition is July 1, 2025.

### Are the standards requirements or recommendations?

The *Prehospital and Out-of-Hospital Standards* contains requirements to be implemented by AABB-accredited programs. A requirement contains the word "shall," which indicates that the statement is mandatory. Failure to meet the requirement would constitute a nonconformance under the AABB Accreditation Program. There are rare instances in which a standard uses the term "may." A statement that uses "may" is not a requirement.

## How does this publication relate to other laws and regulations?

The *Prehospital and Out-of-Hospital Standards* was developed on the basis of good medical practice and, when available, scientific and evidence-based data. The requirements in this book can be followed by a prehospital or out-of-hospital transfusion program located anywhere in the world, but they do not preempt federal, state, and/or local laws and regulations. Accredited facilities must follow the *Prehospital and* 

Out-of-Hospital Standards as written to ensure continued AABB accreditation in good standing. Although the majority of the standards here are intended to be consistent with applicable laws and requirements, no assurances can be given that compliance with the Prehospital and Out-of-Hospital Standards will result in compliance with all applicable laws and requirements. These Prehospital and Out-of-Hospital 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 consulting legal counsel familiar with the issues.

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

Yes. In many standards, the Prehospital and Out-of-Hospital Standards Committee chose to use the term "specified requirements." This phrase is defined in the glossary to include any applicable requirement under which a service might operate. These could include, but are not limited to, a federal regulation, a customer agreement, a practice standard, the instructions for the intended use of a device, or a requirement of an accrediting organization.

## 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 complete reference standard at the end of Chapter 6 to determine what that record must contain.

# What other tools are available to help me implement the *Prehospital and Out-of-Hospital 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 *Prehospital and Out-of-Hospital Standards*.  A crosswalk that cross-references the standards in this edition of Standards for Emergency Prehospital and Scheduled Out-of- Hospital Transfusions with those in the 1st edition of Standards for Out-of-Hospital Transfusion Administration Services.

In addition, users of this edition may want to:

- Visit www.aabb.org for a document that details the disposition and resolution of all comments received to this edition, as well as significant changes. This document is titled "Significant Changes and Response to Comments" to this 1st edition of *Prehospital and Out*of-Hospital Standards. When a public comment is the source of a change, or where the Prehospital and Out-of-Hospital Standards Committee did not make a change suggested by a comment, an explanation is provided.
- Follow guidance for the 1st edition of *Prehospital and Out-of-Hospital Standards*, available online in the AABB Standards Portal and as a printed stand-alone copy of the published *Guidance*. The guidance provides rationales behind significant changes to this edition of the *Prehospital and Out-of-Hospital 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 *Standards* for which they are received. Request forms for variances can be found at www.aabb.org.