PREFACE

he Standards Program Committee (SPC) and the AABB Board of Directors are pleased to present this 1st edition of *Standards for Out of Hospital Transfusion Administration Services* (OHTAS 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 Interpretation Committee, as well as the chairs of the seven specialty program units.

These *OHTAS Standards* were developed by AABB staff under the direction of the AABB Board of Directors, with support from members of the Blood Banks/Transfusion Services Standards Committee. The requirements in this document were developed to be consistent with AABB's *Standards for Blood Banks and Transfusion Services (BB/TS Standards)* and to reflect current practices in out-of-hospital transfusion administration. Accordingly, this 1st edition of *OHTAS Standards* relies on AABB's Quality System Essentials (first identified in Association Bulletin #97-4), which serves as the foundation of all Standards for which AABB provides voluntary accreditation. Users of both sets of Standards will notice some overlap between the quality and technical standards in this document and those in the *BB/TS Standards*.

This 1st edition of *OHTAS Standards* reflects activities performed in by vascular access or infusion service providers in settings other than the hospital, such as long term care facilities, hospices, home care settings and other non-acute care settings. These *Standards* do not address transfusions in pre-hospital settings (such as those that take place in an ambulance or helicopter).

The AABB Board of Directors and AABB staff developed these *Standards*, and the accompanying accreditation program, to recognize that the quality of care with respect to transfusion medicine can and should be extended to patients in non-hospital settings.

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

INTRODUCTION

he Standards for Out of Hospital Transfusion Service (OHTAS Standards) was prepared by the AABB Board of Directors, AABB staff and key volunteers from AABB's Blood Banks/Transfusion Services Standards Committee. The goal of the OHTAS Standards is to maintain and enhance the quality and safety of services provided by out of hospital transfusion services (infusion centers, long term care facilities, hospice or home care settings) and to provide a basis for the accreditation by AABB.

The following frequently asked questions will help users of this publication better understand the 1st edition of *OHTAS Standards*:

When does this edition go into effect?

The effective date of this edition is July 1, 2018.

Are the standards requirements or recommendations?

The *OHTAS Standards* contains requirements to be implemented by AABB-accredited blood banks and transfusion services. A requirement contains the word "shall," which indicates that the statement is mandatory. Failure to meet the requirement would constitute a non-conformance 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 *OHTAS 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 an out of hospital transfusion service located anywhere in the world, but they do not preempt federal, state, and/or local laws and regulations. Accredited facilities must follow the *OHTAS Standards* as written to ensure continued AABB accreditation in good standing. Although the majority of the

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

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

Yes. In many standards, the term "specified requirements" is used. 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 (\mathscr{P}) 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 reference standard at the end of Chapter 6 to determine what that record must contain and the length of record retention.

What other tools are available to help me implement the *OHTAS 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 OHTAS Standards. 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 1st edition. When a public comment is the source of a change, or where a change was suggested but not made, an explanation is provided.
- 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 http://www.aabb.org.