SECTION 1: LICENSE GRANT

Customer’s license to the Blood Bank Software contained herein includes the right to use the Blood Bank Software on a computer system, including peripheral equipment and operating system software (“Designated Environment”) for Customer’s own internal information processing services and computing needs except as expressly permitted by the Agreement, by copying or transferring the same into Customer's Designated Environment and to use any instructions, manuals or other materials, and on-line help files, regarding the use of the Blood Bank Software (collectively “Documentation”) in connection with the use of the Blood Bank Software. Such Blood Bank Software may be used by Customer and such other entities as are expressly permitted by the Agreement only at the specific sites, and by the specific number of concurrent users licensed in the Agreement. This license transfers to Customer neither title nor any proprietary or intellectual property rights to the Blood Bank Software, Documentation, or any copyrights, patents, or trademarks, embodied or used in connection therewith, except for the rights expressly granted herein.

SECTION 2: BLOOD BANK SOFTWARE MAINTENANCE

Blood Bank Software Maintenance also includes corrections to the Blood Bank Software and any Documentation due to defects in the Blood Bank Software or Documentation, as applicable, and improvements to the functionality of the Blood Bank Software made after delivery of the Blood Bank Software but not otherwise separately priced or marketed by Allscripts. All software provided shall be subject to all the terms and conditions of this agreement.

SECTION 3: BLOOD BANK SOFTWARE SOURCE CODE

Notwithstanding any other provisions of this Agreement, in the event Customer acquires the source code from an escrow agent, Customer acknowledges that the Blood Bank Software is a Medical Device regulated by the FDA and as such modifications to Source Code must be made in accordance with applicable Federal Regulations including, but not limited to, 510(k) requirements.

SECTION 4: REGULATORY MATTERS, INTENDED USE

Customer acknowledges and agrees that the Blood Bank Software is a Medical Device subject to government regulation specifically including regulation by the United States Food and Drug Administration (FDA). The Blood Bank Software is intended to be used in accordance with the intended use for which the software received FDA pre-market clearance.

Customer’s use of the Blood Bank Software is also subject to government regulation. By entering into this agreement, Customer represents and warrants that it will comply with all government regulations that are applicable to Customer’s use of the Blood Bank Software. In addition, Customer represents and warrants that it will perform competent clinical intervention, decision making, traceability, and auditing procedures as it relates to the Blood Bank Software. The Blood Bank Software must be installed and validated on the Designated Environment, and used, monitored, and maintained as detailed in the Blood Bank Software’s Documentation and its labeling, specifically including operator user manuals and the other documents related to the proper installation and user training. Customer agrees that whenever it makes claims for the performance of the Blood Bank Software it will do so in a manner consistent with its intended use.

4.1 Reporting Requirements. Customer agrees to promptly notify Allscripts when it becomes aware of any problems with the performance of the Blood Bank Software and/or any complaints from any source about the Blood Bank Software. When requested by Allscripts, Customer will provide a written report detailing the facts related to any such problem or complaint. Customer also agrees to cooperate with Allscripts in any investigation undertaken by Allscripts or designated third party related to a reported problem or complaint specifically including the development of information for Complaint files and compliance with FDA's Medical Device Reporting (MDR) regulations applicable to the Blood Bank Software. Customer will also notify Allscripts prior to filing any MDR which relates to or discusses the Blood Bank Software or any other regulatory report related to the Blood Bank Software. Customer agrees to promptly notify Allscripts at any time the Customer is undergoing a government inspection, including but not limited to, inspection by FDA, that could include government review of the use and/or
performance of the Blood Bank Software and to promptly provide Allscripts with copies of any documents related to such inspection, including but not limited to any Form FDA 483 or report of deficiencies noted in the inspection and the Customer’s response to each. Customer also agrees to give Allscripts notice of any adverse regulatory action taken by FDA or any other governmental authority which includes any allegations or claims related to the Blood Bank Software. In the event of any such adverse regulatory action, Customer agrees to provide Allscripts with copies of any Warning Letter or other document issued by FDA or any other governmental authority that contains allegations or claims related to the Blood Bank Software.

4.2 Blood Bank Software Changes. Customer agrees that it will not make any change or modification to the Blood Bank Software without prior written consent from Allscripts. Customer acknowledges that Allscripts has a regulatory obligation to evaluate each change or modification in light of government requirements applicable to such actions and, if requested by Customer will cooperate with Allscripts and Global Med Technologies in evaluating the significance of any proposed change or modification on the safety or effectiveness of the Blood Bank Software.