DISCLAIMERS

This document does not necessarily reflect the views or policies of the National Association of Community Health Centers (NACHC) regarding HRSA’s implementation of the 340B Program.

Please note: The information presented in this manual is intended to provide the reader with guidance on compliance issues related to the 340B Program. The materials do not constitute, and should not be treated as, professional advice regarding compliance with laws or regulations. The National Association of Community Health Centers and the authors do not assume responsibility for any individual’s reliance upon the information provided in this guide. Regulators may choose to interpret rules and regulations in a manner different than that reflected in this guide. Every effort has been made to assure the accuracy of these materials. However, readers and users should independently verify the applicability of all statements before applying them to a particular fact situation, and should independently determine the correctness of any directive before recommending or implementing it on the health center’s behalf.
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Chapter 1
Introduction

A. Purpose and Limitations

This Manual is intended to provide Federally Qualified Health Centers (FQHCs) with relevant information to assist them with managing their 340B programs to ensure compliance with the federal requirements. The Manual is based on the best information available to the authors at the time of publication and in many instances, the best interpretation of how that information translates into compliant 340B operations. However, it is important to note that:

• This Manual does not constitute, and should not be treated as, professional or legal advice regarding compliance with laws or regulations. Health centers are encouraged to seek external, expert counsel, legal or otherwise, that can adequately take into account the specific factual details of any given situation. Regulators may interpret rules and regulations differently than this Manual. Therefore, the Manual is intended as a reference but not a substitute for individualized, professional advice.

• The Health Resources and Services Administration’s (HRSA) rules and expectations around 340B programs change on a frequent basis. Similarly, HRSA’s interpretations for compliant operation of 340B programs are dynamic. Therefore, the information in this Manual may be superseded by new developments.

• In many key areas of the 340B program, there is currently a lack of clear policy on what HRSA and its Office of Pharmacy Affairs (OPA) expects. In addition, in some areas there is conflicting information on the same issue. In these areas, we have sought to point out the lack of clarity and consistency, and to summarize the range of information received. See Section 1.C for more information. Again, and especially in uncertain areas, we advise health centers to seek out experts to answer questions specific to their circumstances.

• This Manual discusses Federal statutes, regulations, and expectations applicable to all Health Centers; however, health centers must also familiarize themselves and comply with state laws and regulations specific to the practice of pharmacy in their state.

B. Sources

This Manual is based on analysis and input from a range of sources, most notably:

• Section 340B of the Public Health Service Act, and its accompanying Congressional Report.

• Notices in the Federal Register and other guidance issued by the Health Resources and Services Administration (HRSA)’s Office of Pharmacy Affairs, which oversees the 340B program.

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1 The terms “FQHC” and “health center” are used interchangeably in this Manual. These terms are used to refer to entities which are funded under, or have been designated as meeting the requirements of, the Consolidated Health Centers Program, located at Section 330 of the Public Health Service Act. As such, these terms include both grantees and “look-alikes which also encompass health centers that target special populations (persons experiencing homelessness, migrant and seasonal farmworkers, and residents of public housing) as well as health centers that target a general area or population. While clinics operated by tribes, tribal organizations, and Urban Indian Health Organizations qualify as FQHCs, their unique circumstances are not addressed in this Manual.
• The experiences of individual health centers, Primary Care Associations, legal counsel, and accountants with extensive involvement in the 340B Drug Discount Program.

• The Proposed Program Guidance (aka “draft mega-guidance”) that HRSA/OPA published in August 2015. This draft guidance has yet to be finalized, so its proposals are not requirements. However, the Manual discusses the Proposed Program Guidance because it provides additional insight into how HRSA believes the 340B statute should be interpreted, how it operates the Program, and its expectations for compliance.

• The direct experiences of several health centers with significant, long-term experiences in running 340B program. (See Acknowledgements, below.) The text boxes labeled “Peer Perspectives” reflect their direct insights and suggestions.

C. A Very Important Note about 340B Compliance

Relative to other Federal programs – such as the Health Center program, Medicaid, and Medicare – the official rules and expectations around 340B are significantly less clear and evolving rapidly. In many important areas, currently there is a lack of clear policy on what HRSA/OPA expects, and/or how FQHCs are to demonstrate that they are complying with those expectations. At the same time, the level of oversight of the 340B program – including audits by HRSA and by manufacturers – is increasing significantly. As a result, health centers often find it challenging to know what they must do in order to operate in compliance and minimize audit risks.

This Manual is designed to provide accurate and information in regard to the subject matter covered. However, in areas where clear expectations do not exist – and where FQHCs and outside experts may have had varied experiences and/or received conflicting information – health centers will need to carefully evaluate various approaches, considering the benefits and risks of each. On these types of issues, this Manual seeks to highlight the lack of clear policy, the various approaches that a FQHC could take, and the risk/benefits of each. While the Manual is based on the principles of federal law and guidance, this resource is published with the understanding that it does not constitute, and is not a substitute for, legal, financial, or other professional advice. Health centers should consult knowledgeable legal counsel and financial experts to structure and implement their 340B programs in a manner that is appropriate given the particular parties’ respective goals, objectives, and expectations.

D. Acknowledgements

NACHC would like to recognize the following individuals and organizations for their extensive contributions to this Manual:

• Cindy R. DuPree, CPA, Partner, Draffin & Tucker, LLP
• Sue Veer, CEO of Carolina Health Services
• Michael Glomb and Elizabeth (“Issie”) Karan from the firm of Feldesman Tucker Leifer Fidell LLP, (NACHC’s legal counsel)
• The Texas Association of Community Health Centers and its 340Better program
• Carl Taylor, Director of Pharmacy Services, Piedmont Health Services, Inc. Chapel Hill, N.C., Subject Matter Expert, American Pharmacists Association, Peer to Peer Program
• The 340B Pharmacy Services Team at Hudson Headwaters Health Network
• Dan Driscoll, President and CEO, Harbor Health Services, Inc.