

Guidance to 340B providers participating in relief efforts during the Public Health Emergency Declaration by the Secretary

HRSA recognizes that the circumstances surrounding disaster relief efforts warrant additional flexibility to affected 340B entities. An individual receiving 340B drugs must be a patient of the [covered entity as defined by HRSA](#) (PDF - 32 KB). However, the context of the situation may be taken into account in determining whether an individual can qualify to receive 340B drugs during an emergency and meet the patient definition as outlined by HRSA.

In a declared emergency, an abbreviated health record may be adequate for purposes of the 340B Program. The record must identify the patient, record the medical evaluation (including any testing, diagnosis or clinical impressions) and the treatment provided or prescribed. For purposes of 340B Program eligibility, the record may be a single form or note page. It is the recorded information that creates a record. For example, under these circumstances the patient may be without insurance cards or identity papers and providers may not have access to documented medical histories. In the event of a declared emergency, self-reporting of identity, condition and history are adequate for purposes of 340B recordkeeping requirements.

In the event of a declared emergency, where volunteer health professionals are providing health care, emergency documentation should be generated to make the relationship between the provider and the covered entity clear and to make clear the covered entity's responsibility for providing care. This documentation should recognize the emergency nature of the situation, the name and address of the volunteer, and his/her relationship to the clinic, and should be kept on file by the covered entity. A covered entity in an emergency situation should continue to ensure it has policies and procedures in place to address the situation and it must continue to keep auditable records.