additionally asserted that requiring the use of individually-supplied media is prohibited by the Security Rule, based on the risk analysis determination of an unacceptable risk to the confidentiality, integrity and availability of the covered entity's electronic protected health information.

*Response:* We acknowledge these security concerns and agree with commenters that it may not be appropriate for covered entities to accept the use of external portable media on their systems. Covered entities are required by the Security Rule to perform a risk analysis related to the potential use of external portable media, and are not required to accept the external media if they determine there is an unacceptable level of risk. However, covered entities are not then permitted to require individuals to purchase a portable media device from the covered entity if the individual does not wish to do so. The individual may in such cases opt to receive an alternative form of the electronic copy of the protected health information, such as through email.

*Comment:* Several commenters specifically commented on the option to provide electronic protected health information via unencrypted email. Covered entities requested clarification that they are permitted to send individuals unencrypted emails if they have advised the individual of the risk, and the individual still prefers the unencrypted email. Some felt that the ''duty to warn'' individuals of risks associated with unencrypted email would be unduly burdensome on covered entities. Covered entities also requested clarification that they would not be responsible for breach notification in the event that unauthorized access of protected health information occurred as a result of sending an unencrypted email based on an individual's request. Finally, one commenter emphasized the importance that individuals are allowed to decide if they want to receive unencrypted emails.

*Response:* We clarify that covered entities are permitted to send individuals unencrypted emails if they have advised the individual of the risk, and the individual still prefers the unencrypted email. We disagree that the ''duty to warn'' individuals of risks associated with unencrypted email would be unduly burdensome on covered entities and believe this is a necessary step in protecting the protected health information. We do not expect covered entities to educate individuals about encryption technology and the information security. Rather, we merely expect the covered entity to notify the individual that there may be some level of risk that the information in the email could be read by a third party. If individuals are notified of the risks and still prefer unencrypted email, the individual has the right to receive protected health information in that way, and covered entities are not responsible for unauthorized access of protected health information while in transmission to the individual based on the individual's request. Further, covered entities are not responsible for safeguarding information once delivered to the individual.

b. Third Parties

Proposed Rule

Section 164.524(c)(3) of the Privacy Rule currently requires the covered entity to provide the access requested by the individual in a timely manner, which includes arranging with the individual for a convenient time and place to inspect or obtain a copy of the protected health information, or mailing the copy of protected health information at the individual's request. The Department had previously interpreted this provision as requiring a covered entity to mail the copy of protected health information to an alternative address requested by the individual, provided the request was clearly made by the individual and not a third party. Section 13405(e)(1) of the HITECH Act provides that if the individual chooses, he or she has a right to direct the covered entity to transmit an electronic copy of protected health information in an EHR directly to an entity or person designated by the individual, provided that such choice is clear, conspicuous, and specific.

Based on section 13405(e)(1) of the HITECH Act and our authority under section 264(c) of HIPAA, we proposed to expand § 164.524(c)(3) to expressly provide that, if requested by an individual, a covered entity must transmit the copy of protected health information directly to another person designated by the individual. This proposed amendment is consistent with the Department's prior interpretation on this issue and would apply without regard to whether the protected health information is in electronic or paper form. We proposed to implement the requirement of section 13405(e)(1) that the individual's ''choice [be] clear, conspicuous, and specific'' by requiring that the individual's request be ''in writing, signed by the individual, and clearly identify the designated person and where to send the copy of protected health information.'' We noted that the Privacy Rule allows for electronic documents to qualify as written documents for purposes of meeting the Rule's requirements, as well as electronic signatures to satisfy any requirements for a signature, to the extent the signature is valid under applicable law. Thus, a covered entity could employ an electronic process for receiving an individual's request to transmit a copy of protected health information to his or her designee under this proposed provision. Whether the process is electronic or paper-based, a covered entity must implement reasonable policies and procedures under § 164.514(h) to verify the identity of any person who requests protected health information, as well as implement reasonable safeguards under § 164.530(c) to protect the information that is used or disclosed.

Overview of Public Comments

Commenters requested clarification regarding the proposal to transmit an electronic copy of protected health information to another person designated by the individual. In particular, covered entities sought clarification on whether or not an authorization is required prior to transmitting the requested electronic protected health information to a third party designated by the individual. Some commenters supported the ability to provide electronic protected health information access to third parties without individual authorization, while others felt that authorization should be required. Covered entities requested clarification that they are not liable when making reasonable efforts to verify the identity of a third party recipient identified by the individual.

Final Rule

The final rule adopts the proposed amendment § 164.524(c)(3) to expressly provide that, if requested by an individual, a covered entity must transmit the copy of protected health information directly to another person designated by the individual. In contrast to other requests under § 164.524, when an individual directs the covered entity to send the copy of protected health information to another designated person, the request must be made in writing, signed by the individual, and clearly identify the designated person and where to send the copy of the protected health information. If a covered entity has decided to require all access requests in writing, the third party recipient information and signature by the individual can be included in the same written request; no additional or separate written request is