

42 CFR Parts 402 and 403 Medicare, Medicaid, Children's Health Insurance Programs; Transparency Reports and Reporting of Physician Ownership or Investment Interests; Final Rule (February 8, 2013)

42 C.F.R. § 403.912(e) Record retention and audits. (1) Maintenance of records. (i) Applicable manufacturers and applicable group purchasing organizations must maintain all books, contracts, records, documents, and other evidence sufficient to enable the audit, evaluation, and inspection of the applicable manufacturer's or applicable group purchasing organization's compliance with the requirement to timely, accurately or completely submit information in accordance with the rules established under this subpart. (ii) The items described in paragraph (e)(1)(i) of this section must be maintained for a period of at least 5 years from the date the payment or other transfer of value, or ownership or investment interest is published publicly on the Web site.

78 Fed. Reg. 9506-7

Finally, we proposed that in order to facilitate audits and enforcement, applicable manufacturers and applicable GPOs must maintain all books, records, documents, and other materials sufficient to enable an audit, evaluation or inspection of the applicable manufacturer's or applicable GPO's compliance with the requirements in section 1128G of the Act and the implementing regulations. We proposed that applicable manufacturers and applicable GPOs must maintain these books, records, documents, and other materials for a period of at least 5 years from the date the payment or other transfer of value, or ownership or investment interest is published publicly on the Web site.

42 CFR Parts 402 and 403 Medicare, Medicaid, Children's Health Insurance Programs; Transparency Reports and Reporting of Physician Ownership or Investment Interests; Proposed Rule (December 19, 2011)

42 C.F.R. 403.912(d) Record retention and audits— (1) Maintenance of records. (i) Applicable manufacturers and applicable group purchasing organizations must maintain all books, contracts, records, documents, and other evidence sufficient to enable the audit, evaluation, and inspection of the applicable manufacturer's or applicable group purchasing organization's compliance with the requirement to accurately and completely submit information in a timely manner in accordance with the rules established under this subpart. (ii) The items described in paragraph (d)(1)(i) of this section must be maintained for a period of at least 5 years from the date the payment or other transfer of value, or ownership or investment interest is published publicly on the Web site.

76 Fed. Reg. 78758

In addition, we also propose that the Secretary, CMS, OIG or their designees may audit, evaluate, or inspect applicable manufacturers and applicable GPOs for their compliance with timely, complete and accurate submission of information required in section 1128G of the Act and the implementing regulations. Access to this information is implicit in the statute in order to enforce the requirements outlined. To facilitate this review, applicable manufacturers and applicable GPOs must maintain all books, records, documents, and other materials sufficient to enable an audit, evaluation or inspection of the applicable manufacturer's or applicable GPO's compliance with the requirements in section 1128G of the Act and the implementing regulations. We propose that applicable manufacturers and applicable GPOs must maintain these books, records, documents, and other materials for a period of at least 5 years from the date the payment or other transfer of value, or ownership or investment interest is published publicly on the Web site. We believe that 5 years from the date of publication is sufficient for all audit, inspection, or evaluation activities. The requirements set forth in this proposed rule are in addition to, and do not limit, any other applicable requirements that may obligate applicable manufacturers or applicable GPOs to retain and allow access to records.