

POLICY BRIEF

RELEASING MEDICARE CLAIMS DATA TO SUPPORT QUALITY IMPROVEMENT INITIATIVES: LEGAL BARRIERS AND OPPORTUNITIES

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Overview

Health care policy experts believe that measuring and publically reporting information about the performance of physicians and hospitals will be critical in improving the quality of care Americans receive while reining in costs. Community-based organizations around the country, such as those in the Robert Wood Johnson Foundation's *Aligning Forces for Quality* initiative, are demonstrating the concept using private medical claims data. They would like to use Medicare claims data, too — a vast pool of information about how health care is being delivered in America, which, if combined with private data, could facilitate more accurate measurement of providers' performance and better public reports to empower consumers and spur improvements in quality.

Congress is currently considering a number of policy measures to improve quality. Most of these measures would give the Centers for Medicare & Medicaid Services (CMS) new or expanded demonstration authority to test various provider performance measurement, delivery system and payment reform models. However, the Senate bill, as passed on December 24, 2009, also includes a specific provision further authorizing the release of Medicare claims data to "qualified entities." Those entities could use the released information to evaluate and even report on provider performance. If this provision became law and depending on its implementation, it could potentially allow community-based organizations like those in *Aligning Forces* to use Medicare claims data for performance measurement, public reporting and quality improvement activities.

¹ The Patient Protection and Affordable Care Act, H.R. 3590, 111th Cong. § 10332 (2009).

A separate but related question pertains to existing data release authority. Under current rulemaking authority, what kinds of things could the administration do to allow greater release of Medicare data to use for measurement, reporting and improvement? This brief concludes that under current law, CMS has the ability to adopt policies allowing for the release of Medicare claims data for research projects and demonstrations with community organizations that meet standards specified by CMS, including capacity to ensure data security and to safeguard patients' privacy.

Indeed, under its current authority, CMS has developed a number of initiatives involving the release of Medicare data for quality improvement purposes. For example, CMS has moved in recent years — albeit carefully and incrementally — to release Medicare claims data to improve quality and increase efficiency at the physician-practice level.

A series of federal laws govern the release of Medicare data by CMS, including the Social Security Act (SSA), the Health Insurance Portability and Accountability Act (HIPAA), the Privacy Act of 1974, and the Federal Information Security Management Act (FISMA). This brief outlines the relevant provisions of all these and then summarizes current CMS initiatives aimed at promoting broader release of performance data on physicians and other health care providers. It concludes with a discussion of how existing CMS authority can be used to expand access to Medicare data for community-based research or demonstration projects.

Our analysis does not address changes in CMS funding, staffing, oversight or administrative practices that inevitably would be required to facilitate more widespread release of timely Medicare data for ongoing community-based initiatives. Our recommendations merely build on CMS' considerable advances to date and are designed to deal with the threshold legal questions that arise in this type of information-driven reform.

Laws and Regulations Governing the Release of Medicare Claims Data

Several laws are pertinent when considering CMS' authority to release Medicare claims data. These laws are designed to protect individually identifiable patient and physician data, and they span both the SSA as well as other bodies of law that address how health information may be accessed and used by federal agencies and private entities. Medicare claims data, like those maintained by private health insurers, are used primarily to pay claims. The data therefore include confidential information about patients and physicians — and they are protected by the privacy and security provisions of HIPAA, the Privacy Act of 1974 and FISMA. In addition, CMS' authority to release such data derives from the SSA itself. Once the legal authority to release such data has been established, CMS must ensure that each data release complies with the other three applicable laws.

The Social Security Act

The SSA governs the operation of all aspects of Medicare program administration, including the use and release of Medicare claims data by CMS. Specifically, SSA Section 1106(a) provides that "No disclosure ... of any file, record, report, or other paper, or any information ... obtained at any time by the ... agency ... in the course of discharging the duties ... under this Act ... shall be made ... except as prescribed by regulations [prescribed under the Act]." ²Thus, CMS may not release Medicare claims data unless the Act or agency regulations authorize the release.

In addition to this general grant of authority to release data and develop regulations governing data release, the Medicare statute specifically authorizes CMS to release Medicare claims data for purposes of payment,³ research and demonstrations,⁴ and quality improvement efforts undertaken by Quality Improvement Organizations (QIOs).⁵ For these purposes, authorized recipients also include entities that contract to perform functions for CMS, such as Medicare Administrative Contractors,⁶ researchers, and organizations selected for CMS-sponsored demonstrations.⁷

Furthermore, the SSA authorizes the Secretary of the U.S. Department of Health and Human Services to provide beneficiaries with information on the quality of services furnished by physicians and other participating providers and suppliers. Specifically, Section 1851(d)(1) of the Act (relating to Medicare Advantage) requires the Secretary "to broadly disseminate information to current and prospective Medicare beneficiaries on the coverage options provided ... in order to promote an active and informed selection." These coverage options include both the fee-forservice Medicare program (Parts A and B) as well as Medicare Advantage (Part C). Under this authority, CMS may use Medicare claims data, as well as physician performance measurement results generated from Medicare claims data, to provide quality-of-care information to Medicare beneficiaries to help them select coverage arrangements.

HIPAA

² The Social Security Act (SSA) § 1106, 42 U.S.C. §1306(a) (2009).

³ Various authorities, including SSA § 1815. 42 U.S.C. § 1395g (2009) (hospitals); SSA § 1835, 42 U.S.C. § 1395n (2009) (physicians and other Part B providers); SSA § 1853, 42 U.S.C. 1395w-23 (2009) (MA plans); SSA § 1860D-12, 42 U.S.C. 1395w-112 (2009) (Part D plans).

⁴ SSA §1110, 42 U.S.C. §1310.

⁵ SSA § 1154, 42 U.S.C. § 1320c-3.

⁶ SSA § 1874, 42 U.S.C. § 1395kk.

⁷ SSA §1110, 42 U.S.C. § 1310.

⁸ SSA § 1851(d)(1), 42 U.S.C. § 1395w-21(d)(1).

The HIPAA Privacy Rule,⁹ as amended by Sections 13402-13411 of the American Reinvestment and Recovery Act of 2009 (ARRA), protects patient-identifiable health information, often referred to as "protected health information" or PHI. Under the Privacy Rule, only "covered entities" may use and disclose individually identifiable PHI as permitted or required by the rule. (ARRA extends HIPAA protections to business associates as well.)¹⁰ Covered entities include health plans and their business associates, health care clearinghouses, and health care providers that conduct covered transactions. Because CMS is the legal entity operating Medicare Parts A and B, the agency is considered a HIPAA-covered entity under the Privacy Rule.¹¹

At the same time, in its administration of Medicare Parts C and D, CMS does not operate as a health plan; instead, contracted organizations fulfill this role. Thus, where data from Medicare Parts C and D are concerned, the plans, not CMS, would be the covered entities for HIPAA purposes. As such, CMS is considered a hybrid entity.¹²

A covered entity can only use or disclose PHI for a required or permitted purpose — and only to the extent that is necessary for that purpose. Permitted uses include research, treatment, payment and health care operations. The Privacy Rule assigns each term a specific set of meanings. For example, the permitted use for health care operations allows a covered entity to release PHI to conduct quality assessment and improvement activities and to evaluate practitioner and provider performance. In addition to considering whether the release of data is for the purpose of "evaluating" practitioner and provider performance, it is important to recognize that CMS' ability to release data for these HIPAA permitted purposes is constrained by the authority granted under the SSA.

The Privacy Rule also provides covered entities with the authority to enter into contractual relationships with one or more "business associates" under which a business associate can receive the PHI and conduct the functions of the covered entity on its behalf. The Privacy Rule defines a "business associate" as a person acting "on behalf of" a "covered entity or of an organized health care arrangement," performing "activities involving the use or disclosure of individually identifiable health information" or providing a covered entity with "legal, actuarial, accounting, consulting, data aggregation, management, administrative, accreditation, or financial

^{9 45} C.F.R. §§160, 164.504 (2009).

¹⁰ The American Reinvestment and Recovery Act of 2009 (ARRA), Public Law No: 111-5 (2009), § 13404.

^{11 45} C.F.R. § 160.103.

¹² 45 C.F.R. § 160.103. A hybrid entity is defined as a single legal entity that is a covered entity whose business activities include both covered and non-covered functions and that designates health care components in accordance with specified requirements.

¹³ SSA § 1154, 42 U.S.C. § 1320c-3. By law, CMS conducts quality reviews through Quality Improvement Organizations, which are entities that meet the federal requirements and are selected by CMS to carry out quality of care activities.

services," with specified exceptions.¹⁴ Thus, where entities receiving data are acting on CMS' behalf (or on behalf of a QIO or another covered entity), they are authorized to receive and use the data consistent with the terms of their business associate agreements.

In addition, and potentially of greatest relevance to this analysis, absent other laws to the contrary, HIPAA also allows covered entities to release "limited data sets" that are devoid of certain "direct patient identifiers" for research, public health, or health care operations purposes.¹⁵ In the case of patient-identifiable data released for research purposes, no specific consent from patients is required under the Privacy Rule provided the terms of the applicable Systems of Record are met.

The Privacy Act of 1974

The Privacy Act protects information about individuals, such as patients and physicians, held by or collected by the federal government. The Act authorizes a federal agency to release individually identifiable information to identified patients or to their designees with written consent or pursuant to one of twelve conditions of disclosure.¹⁶

One of those twelve conditions of disclosure authorizes federal agencies to release individually identifiable information pursuant to a System of Records (SOR) and Routine Uses that authorize the release of the information.¹⁷ Each SOR is created by the agency that holds the protected data and is subject to a notice and comment process and OMB approval prior to finalization. Existing Routine Uses allow CMS to share individually identifiable information with QIOs, CMS contractors, states, and for other purposes related to research or payment.¹⁸

CMS also has developed a Performance Measurement and Reporting SOR and Routine Uses that authorizes CMS to release individual physician-identifiable information for quality measurement purposes. ¹⁹ This SOR includes Routine Uses involving the release of anonymous patient data from physicians so that performance measurement results can be generated. Projects currently involving the use of these data include the Better Quality Information for Medicare Beneficiaries (BQI) Project, ²⁰ the Generating Medicare Physician Quality Performance Measurement Results

^{14 45} C.F.R. § 160.103.

^{15 45} C.F.R. § 164.514(e).

¹⁶ The Privacy Act of 1974 § 3, 5 U.S.C. 552a(b) (2009).

¹⁷ 5 U.S.C. 552a(b)(3).

¹⁸ 5 U.S.C. 552a(a)(7). See http://www.cms.hhs.gov/PrivacyActSystemofRecords/SR/list.asp?listpage=6 for list of all CMS SORs.

¹⁹ Privacy Act of 1974; Notice of Modified System of Records, 73 Fed. Reg. 80412 (December 31, 2008), amending 72 Fed. Reg. 52133 (September 12, 2007), http://edocket.access.gpo.gov/2008/pdf/E8-31111.pdfas.

²⁰ BQI Project, http://www.cms.hhs.gov/bqi/.

(GEM) Project,²¹ and the Physician Quality Reporting Initiative (PQRI).²² CMS also has notified participating physicians that their claims data may be used to generate performance measures that may be publicly reported beginning January 1, 2009, including satisfactory reporting under the PQRI program and successful e-prescribing as required by the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA).²³

Federal Information Security Management Act of 2002 (FISMA)

The Federal Information Security Management Act of 2002 (FISMA)²⁴ requires that federal information systems and information have security protections commensurate with the risk and magnitude of the harm resulting from unauthorized access, use, disclosure, disruption, modification or destruction of that information. FISMA guidance indicates that FISMA applies broadly to the federal government as well as organizations that possess federal information, but only if they are using it on behalf of a federal agency.²⁵ "On behalf of" has been interpreted to mean that the entity is acting as a "direct extension of the federal government" and "to accomplish a federal government function." ²⁶ As such it applies to systems that support the operations and assets of the agency, including those provided or managed by another agency, contractor or other source.

FISMA includes requirements for security documentation that encompass matters such as systems security plans, risk assessments and contingency plans.²⁷ Systems also must be independently tested and formally certified by the business owners as being in compliance with

²¹ GEM Project, http://www.cms.hhs.gov/GEM/.

²² PORI, http://www.cms.hhs.gov/pgri/.

²³ The Medicare Improvements for Patients and Providers Act of 2008, Pub. L. No. 110-275, 122 Stat 2494 (2008), §§ 131-132.

²⁴ The Federal Information Security Management Act of 2002 (FISMA), Pub. L. No. 107-347, 44 U.S.C. § 3541, et seq. (2009).

²⁵ Policy for Privacy Impact Assessments, Office of the Chief Information Officer, Office of the Assistant Secretary for Resources and Technology, Department of Health and Human Services, Document Number: HHS-OCIO-2009-0002; available at http://www.dhhs.gov/ocio/policy/policy/docs/2009-0002.001.doc.

²⁶ House Report, Commerce Security Act of 1987, H.R. Rep. 100-153, pt. 1 (predecessor to FISMA); See also HHS Memo on FISMA and Grants, Memorandum from Jaren Doherty, Chief Information Security Officer, October 29, 2007, available at: http://oamp.od.nih.gov/NewsEvents/Symposium/Symposium08/Slides/HHSFISMAandGrantsMemo.ppt#257,1,HHS Memo On FISMA and Grants.

²⁷ FISMA, 44 U.S.C. § 3544(b)

security requirements and reviewed at least every three years.²⁸ Security controls for these systems, including contingency plans, must be tested annually.²⁹

FISMA clearly applies to CMS systems and Medicare contractors such as fiscal intermediaries, carriers and Medicare Administrative Contractors. When CMS contractors use the data center for their analytic activities, FISMA governs their activities. Importantly, FISMA does not apply to entities receiving CMS data for work that is not performed on behalf of the government, such as external research requests. However, if a researcher requests individually identifiable data from CMS, it is likely that CMS will require that the entity meet a minimum level of security requirements based on FISMA standards.³⁰

Current CMS Initiatives Aimed at Generating Broader Release of Physician and Provider Performance Information

Using its authority to define lawful data-sharing arrangements, CMS historically has focused on two types of activities: releasing data to its contractors (including its QIOs) to carry out treatment, payment, and health care oversight functions; and releasing data for research and CMS-sponsored demonstrations. At the same time, CMS in recent years has developed additional models that involve the release of Medicare claims data to external entities. For example, CMS has released data to generate consensus-based physician quality measurements. Similarly, the agency has released data to develop performance information for physician practices. Finally, CMS has released institutional performance information on its Compare websites.³¹ In these expanded activities, CMS has sought to use data in more innovative ways and to generate crosspayer comparisons of health care services and payment.

²⁸ Policy for Privacy Impact Assessments, Office of the Chief Information Officer, Office of the Assistant Secretary for Resources and Technology, Department of Health and Human Services, Document Number: HHS-OCIO-2009-0002; available at http://www.dhhs.gov/ocio/policy/policy/docs/2009-0002.001.doc.

²⁹ FISMA, 44 U.S.C. § 3545.

³⁰ See CMS standard Data Use Agreement, http://www.resdac.umn.edu/docs/CMS-R-0235 06 2008.pdf.

³¹ CMS, http://www.medicare.gov/.

Better Quality Information for Medicare Beneficiaries (BQI) Project

Using CMS' authority under §1154 of the Act to release Medicare claims data for QIO-related activities, CMS initiated the BQI project. The agency entered into a contract with a selected QIO to test the most effective methods for combining private-payer data with Medicare administrative data, such as claims, provider, and enrollment files, on 12 pre-selected ambulatory quality-ofcare measures,³² in order to produce more comprehensive and accurate multi-payer measures of quality performance at the physician-practice level. In order to carry out this task, the QIO subcontracted with six community-based collaboratives (known as the "BQI pilots") that had separate access to the private payer data. The goals of this project were threefold: (1) to identify a preferred methodology for combining Medicare administrative data and private-sector claims data for 12 consensus-based, ambulatory care quality measures; (2) to identify a standardized physician attribution methodology at the physician practice level; and (3) to create multi-payer, physician practice level, performance measurement results for 12 measures that were chosen for the undertaking. The BQI pilots were authorized under the terms of their QIO subcontracts to use the results to provide performance information to physician practices and beneficiaries in order to assist them in improving the quality of care delivered and selected. CMS was similarly authorized to release the patient and physician de-identified results under Section 1851(d) of the SSA. The BQI pilots completed their work in October 2008 and a final report was released on October 31, 2008.33

Generating Medicare Physician Quality Performance Measurement Results (GEM) Project

Based on lessons learned from the BQI project and using the same QIO authority, CMS entered into a separate contract with a selected QIO to generate physician practice-level performance measurements for physician practices using Medicare administrative claims data only. The GEM project generated results for the same 12 consensus-based ambulatory care measures used in the BQI project.³⁴ The QIO generated summary measures for each physician practice, rather than the individual patient-level claims data provided to the BQI pilots. The measurement results were first calculated for states where there were community-based collaborations recognized by the Secretary as Chartered Value Exchanges (CVEs).³⁵ CMS also generated similar information for

³² BQI Final Report, Enhancing Physician Quality Performance Measurement and Reporting Through Data Aggregation (2008), http://www.cms.hhs.gov/bqi/ at p.22.

³³ BQI Final Report, Enhancing Physician Quality Performance Measurement and Reporting Through Data Aggregation (2008), http://www.cms.hhs.gov/bqi/.

³⁴ CMS Important Notes and Consideration for Using these Data, Generating Medicare Physician Quality Performance Measurement Results (GEM) Project, http://www.cms.hhs.gov/GEM/Downloads/GEMImportantNotes.pdf. A relatively small number of available consensus-based measures apply to the Medicare population and can be generated solely from claims data.

³⁵ U.S. Department of Health and Human Services, Chartering Value Exchanges, http://www.hhs.gov/valuedriven/communities/valueexchanges/exchanges.html.

all 50 states for calendar years 2006 and 2007 and made this information available on its website for public use relying on its authority under Section 1851(d) of the SSA.³⁶ CVEs and other interested communities may combine the Medicare results with private-sector information generated using the same methodology to produce all-payer information on the specified performance measures.

In addition to the summary measurements provided to CVEs and others, the GEM project also yielded additional information about the quality of care being delivered to Medicare beneficiaries at the national, regional, and zip code levels. For example, the results can be used to compare whether Medicare beneficiaries with diabetes are more likely to receive the appropriate blood test in Maine than in Louisiana. This information enables Medicare beneficiaries to better understand the quality of care they are receiving and better communicate with their providers to facilitate improvement across their community. It also encourages those geographic areas with lower scores to emulate the efforts underway in those areas that show better results.

Physician Quality Reporting Initiative

As authorized by the Tax Relief and Health Care Act of 2006 (TRHCA)³⁷ and extended by the Medicare, Medicaid and SCHIP Extension Act of 2007 (MMSEA)³⁸ and MIPPA,³⁹ CMS designed a physician quality reporting initiative (PQRI), to provide incentive payments to eligible professionals who satisfactorily report data on consensus-based quality measures. For the 2008 PQRI, health professionals could select from among 119 measures on which to report using special codes on their claims. For 2009, physicians had the option of reporting quality data by using special codes on their claims or by reporting information to a clinical registry that in turn submits the quality data to CMS. For 2010, physicians have the option of reporting via the same mechanisms established for 2009 or reporting to CMS via a qualified electronic health record. The number of available measures also has increased to 179. CMS uses the reported information to determine whether reporting is satisfactory and also to generate performance measurement rates. In contrast to the BQI and GEM projects, the PQRI model allows physicians to include clinical information on Medicare claims and this information to be used in calculating the measures. Importantly, the PQRI also relies on physician self-attribution which provides a greater degree of confidence that the physician to whom a measure is attributed is actually the physician who performed the service being measured. Importantly, beginning in 2009 MIPPA also requires CMS to identify those physicians and group practices that successfully report PQRI quality measures and engage in electronic prescribing.

Coordination of Benefits Agreements

³⁶ GEM Project Overview, http://www.cms.hhs.gov/GEM/01 Overview.asp#TopOfPage.

³⁷ The Tax Relief and Health Care Act of 2006, Pub. L. No. 109-432, 120 Stat. 2922 (2006).

³⁸ The Medicare, Medicaid and SCHIP Extension Act of 2007, Pub. L. No. 110-173, 121 Stat 2492 (2007).

³⁹ The Medicare Improvements for Patients and Providers Act of 2008, Pub. L. No. 110-275, 122 Stat 2494 (2008).

CMS currently has Coordination of Benefits Agreements (COBAs) in place with 49 states and the District of Columbia. Through these agreements, CMS releases to state Medicaid agencies Part A and B cross-over claims for dually eligible beneficiaries to achieve payment coordination. Since the fall of 2008, CMS has broadened its COBA agreement with states to allow interested states to request prior written approval from CMS to use the data for quality improvement purposes and to re-release the data for treatment or other quality related purposes.⁴⁰

Compare Websites

In addition to the physician information described above, CMS posts on its suite of Compare websites extensive patient de-identified performance information for other providers. Comparative information is made available on hospitals, nursing homes, home health agencies and dialysis facilities. The flagship Compare website, Hospital Compare,⁴¹ includes all-payer data on the quality of care delivered by hospitals using 30 consensus-based quality measures, including two claims-based outcomes measures for mortality and re-admission;⁴² procedure volume; Medicare reimbursement rates; and patient experience of care based on patient survey data.⁴³

Using Existing CMS Authority to Expand Access to Medicare Data through Community Health Information Partnership Demonstrations

While the law in this area is complex, it is also evident that CMS possesses authority under current law to expand access to Medicare claims data for two basic purposes. The first is improving program operations related to quality and efficiency. As noted above, a series of SSA provisions gives CMS the power to establish data-sharing arrangements under existing laws for the purposes of evaluating program quality, coordinating benefits, encouraging cross-payer comparison of physician performance, enabling physicians to better evaluate their own performance, and giving beneficiaries better information about access, cost and quality. We do not envision this operational authority as offering an avenue for community health information partnerships, simply because community-based entities would not be acting as contractors supporting CMS efforts to carry out its statutory duties.

Rather, these community health information partnerships could better be understood as independent demonstrations aiming to foster the diffusion of reforms to achieve quality and efficiency in community health care systems. In our view, CMS has the power to broaden data access for purposes of research and demonstrations related to innovation in program performance

⁴⁰ State Medicaid Agency Coordination of Benefits Agreement, State Medicaid Director Letter #08-007 (October 3, 2008), available at: http://www.cms.hhs.gov/SMDL/Downloads/SMD100308.pdf

⁴¹ CMS Hospital Compare, www.hospitalcompare.hhs.gov.

⁴² Hospital Compare Quality Measures, see <u>www.hospitalcompare.hhs.gov</u>. The quality measures address heart attack, heart failure, pneumonia, surgical care (e.g., preventing blood clots and infection), and children's asthma.

⁴³ HCAHPS consumer satisfaction survey, see www.hospitalcompare.hhs.gov and CAHPS Hospital Survey, http://www.hcahpsonline.org.

at the community level. CMS could use its demonstration authority to test methods for expanding access to Medicare claims data by community-based quality improvement initiatives whose mission is to affect health-system change among both public and private payers. Such initiatives could be carried out with entities that satisfy CMS conditions of participation and comply with all applicable requirements under HIPAA, the Federal Privacy Act of 1974, and (if determined to be applicable) FISMA.

In our view, an expanded use of CMS' demonstration powers under carefully designed rules would help diffuse into many more communities the very health information enterprise that is at the heart of any effort to improve quality and reduce disparities on a multi-payer basis. The broader availability of data would allow communities to develop and apply selected measures considered by CMS to be consistent with its interest in quality measurement and improvement on a national scale. Indeed, CMS' willingness to allow the customized use of data to improve quality can be seen in its Medicaid COBA agreements, which give state Medicaid agencies considerable leeway to design quality initiatives that comport with measures of quality that are especially important to particular states or localities.

In sum, the highly localized nature of health care makes it essential that the federal government grow the capacity of communities to bring stakeholders together, design multi-payer quality improvement strategies, and then collect data that would permit such strategies to be launched and examined. A CMS demonstration utilizing these community initiatives would appear to be entirely consistent with the agency's fundamental mission in health reform, as well as its legal powers.

For example, building on its QIO-based projects (BQI and GEM) under §1154 of the Act, CMS might develop an initiative that allows regional, community-based, quality improvement organizations to contract with QIOs for multi-payer performance initiatives. Standards governing such contractual arrangements could be developed, with the QIOs and communities conducting their operations in ways that broaden community-level information while still safeguarding patient privacy.

Similarly, CMS might use its research and demonstration authority under §1110 of the Act to develop research projects directly with community-based research entities. Provided these communities are capable of conducting multi-payer research and analysis while safeguarding the information, CMS could use this approach to broaden the availability of community-level or even national information.