

AN INTRODUCTION TO BISCOM DIGITAL FAX

Fast, Secure, and Auditable
Communication of Lab Test Results
Benefits Laboratories, Clinicians
and Patients

BISCOM



Many of today's healthcare providers face common challenges when sharing test results among laboratories, physicians, and patients. Biscom Digital Fax provides a faster and more secure way to accelerate the delivery of clinical diagnostic reports to physicians and patients – that includes the ability to send high resolution color images without fax machines and analog telephone lines. The increases in speed, security, and quality of the output all support the larger goals of improving patient outcomes, increasing patient satisfaction with physicians' services, building loyalty between physicians and clinical laboratories, and enabling laboratories to comply with regulatory and accrediting agencies, including HIPAA, CLIA, and CMS-2319, as well as CAP and OHSA.

Introduction

Medical reference laboratories succeed when they can deliver efficient services and timely results to physicians, enabling physicians to manage their patients promptly. While conducting accurate clinical diagnostic tests, such as MRIs and blood lab, can be time consuming, there are opportunities to reduce wait times for delivering test results to physicians. Reducing wait times accelerates the delivery of quality healthcare to patients and promotes better health outcomes. Additionally, reducing wait times improves patient satisfaction and physician loyalty to the laboratory, helping the laboratory grow and defend its market share.¹ The benefits to each of the key stakeholders are clear:

- **For patients** — Receiving timely and accurate health information for faster and better decision making and planning.
- **For physicians** — Increasing prompt patient management with timely and accurate results, while also engendering loyalty and trust in their partner medical reference laboratories.²
- **For clinical laboratories** — Sending results to physicians more securely is critical to complying with the Health Insurance Portability and Accountability Act (HIPAA) and reduces the providers' risk of a data breach.²
- **For healthcare payors** — Speeding up reimbursements as treatment and follow-up of correctly diagnosed medical conditions is accelerated.³

Current Problems with Secure Lab Report Delivery

The time doctors and patients wait for test results depends not only on the laboratory's turn-around time, but also on the speed at which test data and reports are delivered to the ordering physicians. Stringent regulations prevent both parties from utilizing fast but insecure tools. To maximize the quality of healthcare while minimizing operating costs, laboratories must deliver high-quality diagnostic reports to physicians and patients as securely and efficiently as possible.

Laboratory information systems (LIS) manage patient data within a laboratory, including tracking testing on patient samples and report generation upon completion of the test. The laboratory is responsible for ensuring that patient data is delivered to the intended recipient. Any personally identifying information (PII) or protected health information (PHI) that needs to be transmitted outside the LIS must be sent securely in compliance with HIPAA.⁴

LIS were originally developed to create hard copy reports to be delivered only to the ordering physicians, not to patients or other parties. Older and possibly insecure systems within the healthcare industry make processes inefficient, reducing the quality of healthcare and patient outcomes.

Although some LIS have added the ability to interface with electronic health record (EHR) systems, the tracking and delivery of results are not usually visible. Undetectable tracking becomes a problem because the audit trail, which indicates when and how many times the recipient accessed the files, is also vital to ensure that results are transmitted to physicians and patients with full confidence, and without sacrificing cost and security. Furthermore, laboratories are often strained to cater to physicians with varying preferences with regard to the delivery of results, ranging from hard copies to electronic records.

Reference labs and internal laboratories face different constraints. An internal laboratory primarily performs routine tests and serves the needs of physicians within a hospital or clinic. Hard copy laboratory reports can be routed by internal messengers or printed on local printers directly from internal systems that are integrated with the laboratory. Electronic laboratory reports can be sent within the organization's internal secure email system or directly inserted into the EHR of the patient.

However, reference laboratories, including those that offer highly specialized test services, are seldom connected directly to a healthcare provider's internal network and need more-advanced and secure electronic capabilities to deliver information to physicians caring for patients waiting to be diagnosed and treated.

Alternative Approaches to Delivering Laboratory Results

Physicians care about speed, accuracy, and ease of access of delivered test results. Timely results alleviate patient anxiety and enable prompt delivery of healthcare to those in need.

Methods that laboratories may consider for delivering test results to physicians range from traditional courier services to insertion of electronic laboratory reports into an electronic medical record (see Table 1). To retain the business of their current clients, laboratories must often support multiple methods of delivery that accommodate the varying preferences of physicians and their practices.

Physical delivery methods such as route drivers, courier systems, and US mail are generally accepted practices, but are costly and slow.⁵ Commonly used electronic methods such as email, FTP, and Internet file-sharing services fail to adequately control and safeguard protected healthcare information (PHI), and lack audit trails that can provide a chain of custody for the transfer of information.⁶

Electronic delivery methods, such as secure email over Healthcare Information Exchanges (HIE), which allow healthcare providers and patients to access and securely share PHI offer an alternative to physical delivery methods. However, secure email over HIE or other trusted networks can fail to meet audit trails requirements for certification and inspections, and can be expensive.^{7,8} Additionally, file size limitations imposed by email systems limit transfers of medical images or detailed color graphics.

Other electronic methods, such as web portals connected to LIS and systems developed in-house, can accrue additional costs for integration, deployment, security, and maintenance. Cumbersome processes for setting-up accounts and interfaces that are not user-friendly for clinicians and staff—especially when not typical in their routine clinical workflow—can delay access to test results.

Table 1 | Comparison of Laboratory Report Delivery Methods.

METHOD	CONCERNS	AUDIT TRAIL	SECURES PHI
PHYSICAL DELIVERY METHODS			
Route driver (reports dropped off when new samples are picked up)	High staff costs to prepare packages	Not always— when reports left in lock box	Yes
Courier systems (local or national carriers such as FedEx)	Time-consuming; high costs for printing and packaging	Yes, if package must be signed for	Yes
US Mail	High cost of printing and packaging; letters can be delivered to the wrong address; post office will not indemnify the lab against the liability for lost packages	No, unless certified with return receipt	Maybe
ELECTRONIC DELIVERY METHODS			
Fax	Quality of faxed documents may be insufficient for diagrams or images	Yes, if done with fax servers and services	Yes, if done with fax servers and services
Color Fax	Color fax machines are very uncommon due to high data requirements and low speed telephony modem connections.	Yes, if done with fax servers and services, but not readily available	Yes, if done with fax servers and services, but not readily available.
Biscom Digital Fax	None	Yes	Yes
Secure e-mail over healthcare information exchanges (HIE) or other trusted networks	Laboratory may not have access to the HIE or trusted network used by provider	No	Yes, but during transmission only
Web portal connected to LIS that physician can use to download laboratory reports	Difficult and costly to develop/customize/maintain	Yes	Yes
Secure file transfer protocol (SFTP)	Requires additional development to create audit trails	No	Yes, but during transmission only
Biscom Secure File Transfer	None	Yes	Yes
Other ad-hoc methods (remote printing, data CDs, VPN connections)	May not be cost effective at scale	Maybe	Maybe
UNACCEPTABLE METHODS			
E-mail with a file attachment	Inadequate PHI controls	No	No
File transfer protocol (FTP) protocol for copying files between two directories across a network connection	Inadequate PHI controls	No	No
Internet file sharing services	Inadequate PHI controls	No	No

HIPAA and Other Challenges

While patients may be more concerned about getting prompt medical care, this does not preclude them from taking legal actions if their privacy rights are violated. HIPAA violations can result in significant damages assessed to the healthcare organization.⁹ The Office of Civil Rights investigates instances in which patients may have been harmed by a breach of privacy.

Some considerations for laboratory test data:

- Any ePHI from the inception of the data in the lab to its access by the physician's office, the patient, or the patient's designated caregiver falls under the governance of HIPAA.¹⁰
- Any electronic transmission of PHI must be done securely.¹¹
- PHI—as well as operating procedures used to gather, process and distribute PHI—must always remain secure. In case of a possible violation and subsequent investigation, maintaining adequate audit trails is essential.¹²
- Casually or accidentally transmitting information without tracking previous successful or failed transmissions is highly risky, even if the method of transmission appears to be secure.

Beyond HIPAA, the ability to provide a detailed audit trail is essential for other reasons, including laboratory regulatory and accrediting agencies. Laboratories are required to present policies and procedures that control access to patient information during Clinical Laboratory.

Improvement Amendments (CLIA) and College of American Pathologists (CAP) audits to gain and maintain certification, as well as the Occupational Safety and Health Administration (OSHA).¹³ Additionally, state healthcare agencies, especially those with aggressive reach policies such as New York, will investigate any laboratory that holds medical records of their taxpayers located anywhere, without respect to state lines.¹⁴ Unannounced surveys are also common and laboratories are obliged to prove that they are in control of PII, PHI, or any other information that can identify the patient in association with medical records or laboratory test results.¹⁵

Beyond requirements from regulatory and accrediting agencies and state agencies, when customer service staff needs to track down the status of test results for a patient, the audit trail is vital.

Finally, CMS-2319 requires that laboratories provide test results directly to patients. While most laboratories have workflows and systems that are optimized to deliver laboratory reports only to physicians, laboratory report requests from patients have increased. Now, laboratory customer service groups often process requests from patients manually, typically by printing out laboratory reports and mailing them to patients, at considerable cost.

Because laboratory customer service typically cannot store PII or PHI in cloud-based customer relationship management (CRM) systems, they need separate methods to access and send laboratory reports. As patients become more aware of their rights and directly request lab results, CMS-2319 implicates that laboratories must invest in systems that will meet the increase in laboratory test result requests.

Biscom Digital Fax as a Solution

Biscom Digital Fax offers rapid delivery of laboratory results without compromising privacy. Biscom Digital Fax is a breakthrough document delivery technology solution from Biscom, the trusted choice of healthcare organizations, government, and large enterprises for secure document delivery. The solution supports all standard file types including text, PDF, Microsoft Office documents, and images, and adds:

- Absolute security and data integrity that qualifies as legally binding in a court of law
- Absolute best quality image that does not use a lossy image format such as JPEG

Previously, the superior resolution of a faxed (TIFF) image was offset by its large file size. With Biscom Digital Fax, that disadvantage is overcome, as the final image received is a relatively small PDF file. In addition, with Biscom Digital Fax there are none of the packet loss and data compression problems inherent in faxing over a VoIP network.

Documents transmitted with Biscom Digital Fax can be received and printed in hard copy form or as digital documents that can be viewed on a computer screen or mobile device.

Reporting and Security

For auditing such as CLIA and CAP, as well as investigations by state agencies, Biscom Digital Fax provides comprehensive audit trails and reporting – both essential components to keeping track of when and how many times the intended recipient accessed files.¹³

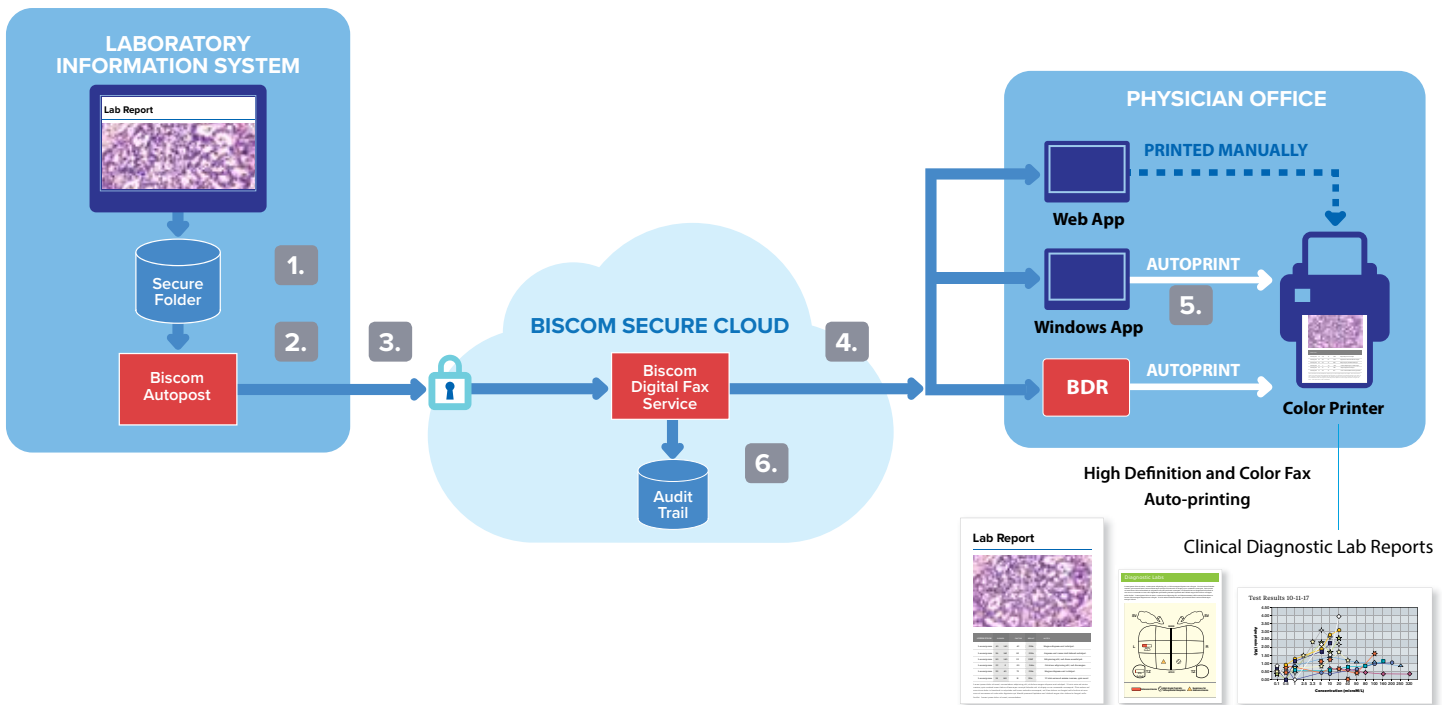
Additionally, the separation of software components with a multi-tier architecture and secure Web service APIs avoids exposing inbound connections to the LIS from the open Internet. Furthermore, laboratory test reports remain encrypted until the physician or patient opens the reports. These capabilities help ensure PHI is accessed by the intended recipient, keeping information secure.

Delivery Variety to Reduce Time and Costs

Not every provider prefers the same method for report delivery, and each method can vary in terms of time, resources, and costs. For example, while some providers turn to adding a Web portal to an existing LIS, Biscom Digital Fax can be set up to work with an existing LIS to send laboratory reports to physicians without complex integration (see Figure 1).

Further reducing complexities, Biscom Digital Fax can deliver reports in the original format that was generated by the LIS, instead of a generic reformatted report created by an EHR system. This is especially critical for tests involving complex data that needs to be presented exactly as the laboratory created the report. Examples include blood tests that are generally reference ranges and can be imported into a practice's EMR, pathology reports, which contain interpreted text that is formatted for readability by the laboratory, and genetic tests, which chart drug interactions.

Figure 1 | Sending Lab Reports to Physicians



1. The LIS deposits files in a secure folder behind the lab’s firewall.
2. Biscom Digital Fax Autopost, a lightweight application that automates submission of production jobs to Biscom Digital Fax, runs behind the firewall on a system that has access to the folder.
3. As the LIS creates lab reports and deposits them into the folder, Biscom Autopost automatically extracts the lab reports from the folder and sends them to the Biscom Digital Fax Service server via a Web Services REST API over a secure connection.
4. As Biscom Digital Fax receives the data, it renders the documents into color, high-resolution, encrypted fax images stamped with date time on each page and completes electronic delivery of the lab reports to ordering physicians’ offices.

5. The lab reports are automatically printed on a color printer in the physicians’ offices by Biscom Document Router(s) or the Biscom Digital Fax Windows App; they can also be viewed on-screen by the Biscom Digital FaxWindows App, Web App, or Mobile App (iOS and Android).
6. When the physicians’ office receives or views the lab reports, Biscom Digital Fax creates entries into the audit trail record.

Printing and Color

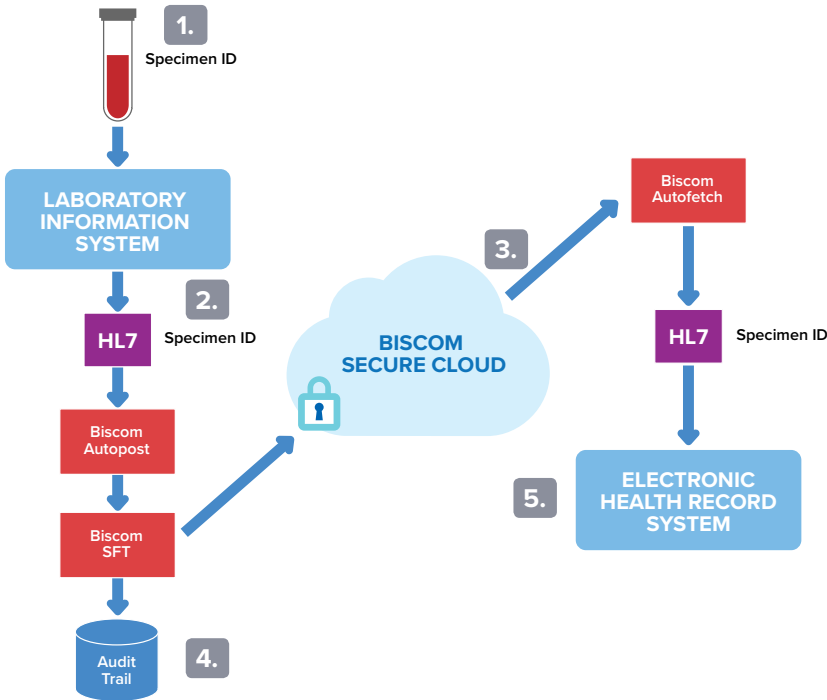
There are a number of costs incurred with physical methods such as couriers and the expenses associated with printing and packaging high-resolution and colored documents. However, Biscom Digital Fax offers several solutions to reduce the time and costs of delivery. Biscom Digital Fax transfers high-resolution and color clinical diagnostic laboratory reports such as anatomic pathology/oncology, histology, genetic, and radiology tests, which have more graphical elements than typical numeric clinical tests.

Laboratory test reports can be printed out or imported into a patient's electronic health record by the healthcare provider. Moreover, recipients may attach a Biscom Document Router to a local or network printer to automatically print laboratory reports (see Figure 1) right in the physician's office, or be viewed by a clinician on a computer display or mobile device.

Some healthcare providers may prefer that a laboratory send HL7-encoded files formatted for their EHR systems to enable direct import of laboratory results into patient records.¹⁶ In this case, healthcare providers may utilize Biscom AutoFetch, which can receive such files automatically from Biscom Secure File Transfer (Biscom SFT), a related solution from Biscom for transferring files, over a secure connection and make these available to the provider's EHR system.

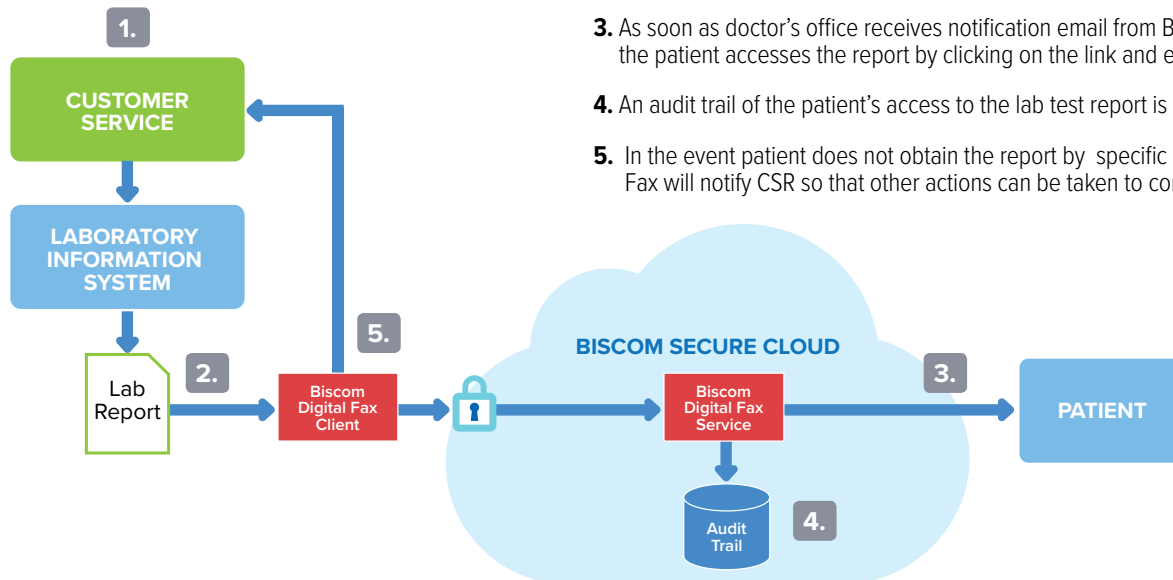
Another case is when a patient requests a laboratory report directly from the laboratory, in accordance with CMS-2319.25 Laboratory customer service can use the Biscom Digital Fax Web App to send a copy of the report to the patient (see Figure 3).

Figure 2 | Secure File Transfer to EHR



1. A unique identifier, e.g. an order number or specimen number that does not contain PII, is assigned to the specimen at the time of the order by the provider.
2. The LIS generates the lab test results in HL7 format, with the unique identifier, and drops it into a secure folder in the lab.
3. Biscom SFT Autopost picks up the HL7 files, sends it to Biscom SFT, which then sends another file securely the healthcare providers.
4. From the healthcare provider, Biscom SFT Autofetch obtains the document from Biscom SFT, places the HL7 in a secure folder at the provider; an audit trail of the delivery is created in the laboratory by Biscom SFT.
5. Using the unique identifier to distinguish the correct patient from the lab order, the healthcare provider imports the HL7 file into their EHR system, and injects the lab test result data into the correct patient record.

Figure 3 | Sending Lab Reports to Patients



1. Laboratory Customer Service Representative (CSR) receives request for copy of laboratory test report from patient.
2. CSR pulls a copy of report from LIS and uses Biscom Digital Fax Web App to deliver to patient.
3. As soon as doctor's office receives notification email from Biscom Digital Fax Service, the patient accesses the report by clicking on the link and entering a password.
4. An audit trail of the patient's access to the lab test report is recorded.
5. In the event patient does not obtain the report by specific deadline, Biscom Digital Fax will notify CSR so that other actions can be taken to comply with CMS-2319.

In addition to ordering physicians and patients, other authorized parties may need to obtain copies of test reports. Some of these parties may include:

- **Referring Physicians** — other physicians managing a patient may need to obtain a copy of the laboratory test result for reference.¹⁷
- **Recovery or Long-Term Care facilities** — if the patient is transferred from a hospital to another facility for care, the physicians in charge may need to refer to copies of laboratory test results.¹⁸
- **Healthcare Payors** — consulting physicians for healthcare insurance companies may ask to review laboratory work to authorize payment.¹⁸
- **Legal System** — a lawyer representing a patient, physician, or healthcare practice may need access to laboratory reports.¹⁹

The laboratory can use Biscom Digital Fax to rapidly distribute laboratory data and reports to these authorized third parties without going through elaborate steps to communicate the information securely. When this is done, an audit trail of each delivered lab report is created automatically by Biscom Digital Fax.

Conclusion

In healthcare, improving patient care is a top priority, particularly when it leads to superior health outcomes. Biscom Digital Fax provides a communications solution that delivers higher quality reports to ordering physicians promptly, cost-effectively, and securely, while also providing comprehensive audit trails that laboratories require to meet compliance and certification requirements.

About Biscom

The National Institutes of Health, Cedars-Sinai, Dana Farber, Massachusetts General Hospital, and Boston Children's Hospital and over 4000 other organizations rely on Biscom solutions for their secure document delivery needs. As a pioneer of fax solutions, Biscom continues to develop innovative fax and secure document delivery solutions that improve business process and enhance data security. Biscom's solutions are backed by our responsive technical support team, which is located at Biscom's corporate headquarters just outside of Boston, Massachusetts.

For more information about Biscom's faxing solutions please visit Biscom.com or email info@biscom.com.

References

1. Shannon J. McCall, Rhona J. Souers, Barbara Blond, and Larry Massie (2016) Physician Satisfaction With Clinical Laboratory Services: A College of American Pathologists Q-Probes Study of 81 Institutions. *Archives of Pathology & Laboratory Medicine*: October 2016, Vol. 140, No. 10, pp. 1098-1103.
2. Jones, B., Bekeris, L., Nakhleh, R., Walsh, M. and Valenstein, P. (2009). *Physician Satisfaction With Clinical Laboratory Services*. [online] [Archivesofpathology.org](http://www.archivesofpathology.org). Available at: <http://www.archivesofpathology.org/doi/pdf/10.1043/1543-2165-133.1.38> [Accessed 20 Jun. 2017].
3. Gruessner, V, ed. How Payers Should Prepare for Value-Based Reimbursement. *HealthPayer Intelligence*. July 2016. <https://healthpayerintelligence.com/features/how-payers-should-prepare-for-value-based-reimbursement>. [Accessed 03, Dec. 2017]
4. HHS.gov. (2017). *Cloud Computing*. [online] Available at: <https://www.hhs.gov/hipaa/for-professionals/special-topics/cloud-computing/index.html> [Accessed 20 Jun. 2017].
5. Darkdaily.com. (2012). Clinical Pathology Laboratories Beef Up Courier and Logistics Services to Deliver More Value to Client Physicians | Dark Daily. [online] Available at: <https://www.darkdaily.com/clinical-pathology-laboratories-beef-up-courier-and-logistics-services-to-deliver-more-value-to-client-physicians-40612> [Accessed 20 Jul. 2017].
6. Guide to Privacy and Security of Electronic Health Information. (2015). 2nd ed. [ebook] The Office of the National Coordinator for Health Information Technology (ONC), pp.30-31. Available at: <https://www.healthit.gov/sites/default/files/pdf/privacy/privacy-and-security-guide.pdf> [Accessed 17 Jul. 2017].
7. Biddle, S. (2017). *Securing Healthcare's Move to the Cloud - HITECH Answers: Meaningful Use, EHR, HIPAA News*. [online] HITECH Answers: Meaningful Use, EHR, HIPAA News. Available at: <https://www.hitechanswers.net/securing-healthcares-move-cloud/> [Accessed 18 Jul. 2017].
8. The Business Case for Interoperability and Health Information Exchange. (2014). [ebook] Healthcare Information and Management Systems Society (HIMSS), p.9. Available at: <http://himss.org> [Accessed 18 Jul. 2017].
9. Ama-assn.org. (n.d.). *HIPAA Violations & Enforcement | AMA*. [online] Available at: <https://www.ama-assn.org/practice-management/hipaa-violations-enforcement> [Accessed 19 Jul. 2017].
10. HHS.gov. (1996). *Summary of the HIPAA Privacy Rule*. [online] Available at: <https://www.hhs.gov/hipaa/for-professionals/privacy/laws-regulations/index.html> [Accessed 19 Jul. 2017].
11. Pittenger, M. (2017). Data-centric Security for Healthcare Compliance. [online] Digital Guardian. Available at: <https://digitalguardian.com/blog/data-centric-security-healthcare-compliance> [Accessed 19 Jul. 2017].
12. Walsh, Tom; Miaoulis, William M. "Privacy and Security Audits of Electronic Health Information (2014 update)" *Journal of AHIMA* 85, no.3 (March 2014): 54-59.
13. U.S Government Publishing Office (2017). *Electronic Code of Federal Regulations*. pp.Title 42, Chapter IV, Subchapter G, Part 493.

14. Dunham, C. (2015). *Compliance Advisor for Clinical and AP Laboratories and Pathology Practices*. [PDF] Plain Language Media LLLP, pp.1 & 5. Available at: http://www.ebglaw.com/content/uploads/2015/08/Dunham-Varying-State-Requirements-Applicable-to-Independent-Clinical-Labs-GCA_Jun_2015_CDunham-article.pdf [Accessed 19 Jul. 2017].
15. Food and Drug Administration (2010). *Information Sheet Guidance For IRBs, Clinical Investigators, and Sponsors FDA Inspections of Clinical Investigators*. Silver Spring, MD: U.S. Department of Health and Human Services Food and Drug Administration, p.3.
16. Rowley, R. (2010). *How does HL7 fit into EHR / EMR interoperability?*. [online] Practicefusion.com. Available at: <http://www.practicefusion.com/blog/how-does-hl7-fit-into-emr/> [Accessed 20 Jul. 2017].
17. Medicalmutual.com. (n.d.). *Communication Between the Referring and Consulting Physician*. [online] Available at: <https://www.medicalmutual.com/risk/practice-tips/tip/communication-between-the-referring-and-consulting-physician/45#One> [Accessed 20 Jul. 2017].
18. Beck, M. (2014). Drug Treatment Swept Up in Push for Medical-Records Sharing. *Wall Street Journal*, [online] p.Single page. Available at: <https://www.wsj.com/articles/drug-treatment-swept-up-in-push-for-medical-records-sharing-1401927141> [Accessed 18 Jul. 2017].
19. HHS.gov. (2017). *Individuals' Right under HIPAA to Access their Health Information*. [online] Available at: <https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/access/index.html> [Accessed 20 Jun. 2017].

BISCOM www.biscom.com

© All rights reserved. Biscom and all Biscom product names are trademarks or registered trademarks of Biscom Inc. All other company and product names are trademarks or registered trademarks of their respective companies.