



Laboratory Compliance Training

UCLA Health System

Department of Pathology and
Laboratory Medicine

Revised 1/2010



Objectives

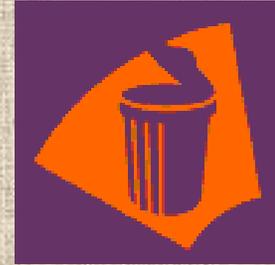
- Understand why a voluntary compliance program is important
- Determine your compliance role in the laboratory and be able to help prevent fraud and abuse from occurring in the laboratory
- Understand the consequences of violating the law and the compliance policies of the laboratory
- Recognize compliance problems and issues even when they are not a component of your direct role in the laboratory



What Is a Voluntary Compliance Program

- A voluntary compliance program is created by a laboratory based on the Office of the Inspector General's (OIG's) published guidance
- It will reduce or eliminate improper billing to Medicare and prevent criminal activities
- If a laboratory develops and implements an effective compliance program it will receive special consideration should a problem arise involving a government investigation

Introduction



- The government believes that fraud, abuse and waste exist in the healthcare industry today because of cases it has settled and prosecuted
- All healthcare providers, including laboratories, make billing errors
- The Office of Inspector General (OIG) believes that honest members of the healthcare community can police themselves if they receive guidance
- The OIG has published Compliance Program Guidance documents for health care providers, including laboratories

Laws and Regulations that Govern Laboratories



- **Social Security Act**
 - Medicare and Medicaid laws are in this act
 - Medicare rules and regulations come under this act
- **Anti-kickback laws**
 - Provide criminal penalties for individuals or entities that knowingly and willfully offer, pay, solicit or receive money or favors for referrals of tests or services that will be paid for by the Medicare or Medicaid programs
- **False Claims Act**
 - Provides criminal penalties for knowingly or willingly filing a false claim to a government program

Laws and Regulations (Continued)

- Self Referral (Stark) laws and regulations
 - Identify financial relationships that have the potential to result in directed referral to one or both of the individuals or entities involved
 - Prohibit the referral of patient or tests between related entities unless certain conditions are met
- Health Insurance Portability and Accountability Act (HIPAA)
 - Prohibits health care providers and payers from improper or inappropriate use of a patient's confidential health information
 - Requires health care providers to ensure that a patient's confidential information is kept secure
 - Provides for standardized electronic formats for all health care transactions



Risk Areas

- The government identifies laboratory activities it considers high risk areas for compliance problems
- The UCLA laboratory compliance program focuses on these areas
- Employee training and education lists and explains each of these risk areas

Billing and Medical Necessity

- Billing
 - Highest risk activity a laboratory has; all laboratory activities contribute to the billing process
 - Many of the risk areas included in this program are components of the billing function
- Medical Necessity
 - Medicare is only allowed, by law, to pay for tests that are reasonable and necessary for the diagnosis and treatment of disease
 - Medical necessity is an underlying principle of the Medicare program
 - Most tests performed for screening or routine exams are not considered medically necessary by the Medicare program



Coding

- CPT (Current Procedural Terminology) codes are used to describe specific tests or services
 - The amount of payment for a test is dependent on the CPT code
 - It is against the law to use the wrong CPT code for a test to cause or increase payment for the test
- ICD-9CM (International Classification of Disease, 9th Editions, Clinical Modification) codes are used to classify diseases and conditions and describe signs, symptoms and medical circumstances
 - ICD-9CM codes are used to indicate the medical necessity of a particular test
 - It is against the law to use the wrong ICD-9CM code for the purpose of causing or increasing payment for a test

National Coverage Decisions (NCD)

- NCDs are developed to describe the circumstances for Medicare coverage *nationwide* for a specific medical service procedure or device.
- Became effective on 11/25/02
 - Pertains to specific laboratory tests
 - Acceptable ICD-9s – reasonable and necessary for the treatment and diagnosis of injury or illness (Note: Medicare will deny payment unless provider obtains “approved” ICD-9 code)

List of Laboratory NCDs

- Culture, Bacterial, urine
- HIV testing (prognosis, monitoring)
- HIV testing (diagnostic)
- Blood counts
- Partial thromboplastin time
- Prothrombin time
- Serum iron studies
- Collagen crosslinks
- Blood glucose testing
- Glycated hemoglobin/protein
- Thyroid testing
- Lipids
- Digoxin, therapeutic drug assay
- Alpha-fetoprotein
- Carcinoembryonic antigen
- Human chorionic gonadotropin
- Tumor antigens by immunoassay including CA 125, CA 19-9, C 15-3/CA 27.29
- Prostate specific antigen
- Gamma glutamyl transferase
- Hepatitis panel/Acute hepatitis panel
- Fecal occult blood

Medical Coverage Policies (LMRPs)

- LMRPs (Local Medical Review Policies) are published by Medicare for some laboratory tests
 - Developed for tests that can be used for screening or diagnosis of disease
 - CPT codes describe laboratory tests and ICD-9CM codes determine when coverage is allowed
 - If an LMRP test is ordered by a physician, an ICD-9CM code that is included in the LMRP must be given to the laboratory or the Medicare program will not pay for the test
 - It is against the law for the laboratory to change or add an ICD-9 code submitted by a physician
 - The Balanced Budget Act of 1997 made it illegal for physicians to order LMRP tests and not supply an ICD-9CM code with the order

Advance Beneficiary Notices (ABNs)

- Advance Beneficiary Notices (ABNs) allow laboratories to bill Medicare patients directly for specific tests that are not covered by Medicare



ABNs (Continued)

- A laboratory cannot bill a Medicare Beneficiary for a laboratory test unless it notifies the patient in writing that Medicare is not going to pay for the test
- This notice is called an ABN
- The beneficiary can choose not to have the test performed if they do not want to pay for it
- Laboratories cannot make all Medicare beneficiaries sign ABNs
- The ABN must contain the specific name of the test
- The ABN must give a specific reason the laboratory thinks payment for the test will be denied
- The beneficiary should sign the ABN and be given a copy



UCLA Health System Expectations

- Not sharing passwords
- Not clocking in for someone else; honestly reporting the time worked
- Preventing to the best of your ability any unauthorized access to patient's information
- Respecting the confidentiality, financial, medical and personnel information of patients, faculty, staff, students and the institution
- Reporting unsafe conditions or equipment
- Disclosure of potential or actual conflicts of interest

Departmental Culture

- The Department's culture is one of trust and cooperation. It is every employee's responsibility to support this culture by:
 - Respecting all people and treating them fairly
 - Not working under the influence of alcohol or drugs
 - Not accepting gifts/benefits appearing or meant to influence your job
 - Never accepting personal gifts of cash



Confidentiality

- All employees have a responsibility to maintain the confidentiality of medical information
 - Medical information should never be discussed outside of the laboratory
 - It should only be discussed with the ordering doctor or an authorized representative of the doctor
 - Employees should verify the identity of the individual requesting such information
- Employees who communicate with patients, physicians or their office staff, insurance company representatives or government employees about any laboratory activity should only give information they know to be true and accurate
 - Employees should never give false information and should never guess the answer to any question
 - In case of doubt, refer the person to a Supervisor

Health Insurance Portability and Accountability Act (HIPAA)

- The information collected on patients when they come for services is confidential and must be protected
- To help ensure this you should not read patient information unless you have a work related, “need to know” reason to do so
- Any patient information you may overhear you should not share with co-workers or people outside of UCLA Health System locations

HIPAA (continued)



- If you see someone you know come to the clinic or hospital for healthcare, it is not appropriate to talk about their patient information to anyone not involved in their care
- You should not ask other employees to look up information about patients in the Medical Center, including you or your family
- Keep your computer screens out of the public eye and do not leave identifiable patient information in locations where it can be seen by anyone not specifically involved in that patient's care



HIPAA (continued)

- Shredding bins are available for use by employees when discarding anything that contains confidential information
- If you find any stray patient information, you should give it to your Supervisor
- HIPAA penalties from the government include criminal charges and monetary fines to individuals (potentially up to 10 years imprisonment and \$250,000 in fines)

Security of Patient Information

- Verification should be obtained PRIOR to releasing patient information whether request is in person, by phone or electronically
- Fax cover sheets should be utilized with each internal and external transmission
- When releasing patient information to outside agencies as required by law, the employee must document what information was disclosed

Information Systems Security

- UCLA information systems are monitored for inappropriate activity
- Employees are accountable for the use and activities performed with their password
- It is never appropriate to use the information system for activities such as chain letters, solicitations, campaign material, etc.





Requisitions

- Requisitions must be designed to ensure that ordering physicians can choose tests that are medically necessary for their patients
 - Requisitions should contain reminders about Medicare rules of medical necessity and list the contents of panels and profiles
 - Requisitions must provide a place for the physician to include the diagnosis (ICD9-CM) codes
 - Physicians should be encouraged to use only the requisitions supplied by the laboratory to order tests



Ambiguous Orders

- Ambiguous or unclear test orders
 - When the orders for a test are not absolutely clear, the laboratory must contact the ordering physician to clarify the orders before performing and billing for the test
 - The laboratory cannot guess at the order
 - The laboratory cannot perform and bill for tests that are not specifically ordered
 - The laboratory cannot change a physician order without contacting the physician
 - In any case where specimen integrity or patient care will be compromised by a delay in testing, follow the policies the laboratory has established for such cases

Tests Performed/Ordered Correctly

- The laboratory has a system in place to detect tests that are not performed due to a laboratory error and stop or credit the billing for these tests
 - The laboratory cannot bill for tests that are not performed
 - Employees aware of a test being canceled or not being performed for some reason must follow the policies and procedures associated with correcting the billing
- The laboratory only performs tests that are ordered by individuals authorized to order tests
 - If an employee knows that a test has been ordered by someone other than an authorized individual, the employee should report it to their Supervisor or the Compliance Officer



Written and Verbal Orders

- All tests must have a written order on file
 - Any verbal order for tests including tests added on to a specimen already in the lab, must be followed up by a request for a written order
 - Employees who receive verbal or add-on orders must follow procedures to ensure that a follow-up written order is requested
 - It is against Medicare regulations to bill extra for calculated test results; only appropriate tests actually performed may be billed
 - It is against the law to bill for the same tests or services twice (duplicate billing)
 - It is against the law to bill for quality control tests or tests performed multiple times to check or verify the results

Physician Notices/Acknowledgements

- Notices to physicians must be sent by the laboratory to its customers once each year
 - Notices remind physicians about Medicare rules and regulations
 - Notices include summaries of laboratory test ordering policies, requisition use, CPT and ICD coding
- UCLA does not use customized test panels, therefore, physician acknowledgements are not required





Documentation

- Documentation and compliance activities are the responsibility of all employees
 - All forms must be completed and properly filed
 - All procedures must be followed and properly documented
 - If documentation of compliance activities cannot be established during an audit or investigation, the government will assume that the compliance program is not being followed



Test Release

Release of test results by phone, fax and other non-routing methods:

- Employees should release test results to the person who ordered the test
- Never release the results of a test to a patient unless authorized in writing by the ordering physician

Reporting Concerns

- If you have any compliance concerns, attempt to resolve them first at the Supervisory level.
- If you have questions, or complaints regarding the privacy of patient information or compliance concerns, you can contact the Chief Compliance or Privacy Officer with your concerns.
- The confidential Compliance Hotline number is (800) 296-7188 and can be called at any time.

Laboratory Compliance Scenarios



Unresponsive Supervisor

Joe recently attended a compliance workshop and is concerned that one of the lab's billing protocols may be incorrect (e.g., billing separately for a UA dip and urine microscopic when the dip is positive and a microscopic is then performed as a reflexive test). He brings this issue to his Supervisor's attention, and his Supervisor responds by saying that "this is how we do it here" and turns away. It is obvious the supervisor is not going to address the issue. What should Joe do now?

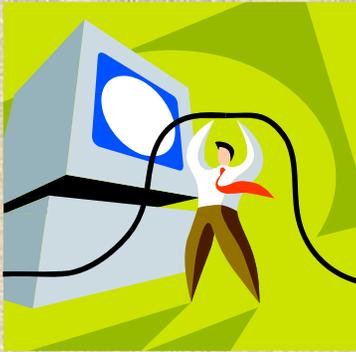


Answer

- A. Forget about it, since his Supervisor does not think it is important and he doesn't want to get in trouble
- B. Call the Compliance Hotline at 1-800-296-7188
- C. Contact the laboratory's Compliance Manager at 310-825-5196
- D. Contact the Hospital Compliance Office at 310-825-7135
- E. B, C and D are all options

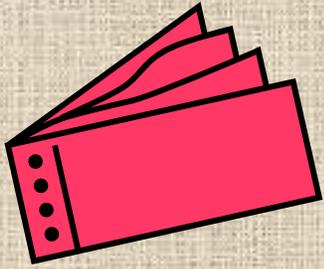
PPI and Computer Access

Ann has asked Joe to look up a biopsy result in the computer for their co-worker and friend John because she is concerned about his health and wants to know what to say in a “get well” card and find out how to contact him at home. She doesn’t have computer access herself. What should Joe do?



Answer

Joe should explain to Ann that this information is protected healthcare information and they could both be fired if he does what she requests. He might recommend that Ann ask their Supervisor if a “get well” card is being sent to John and, if so, request that she be allowed to enclose a personal message.



Free Tickets?

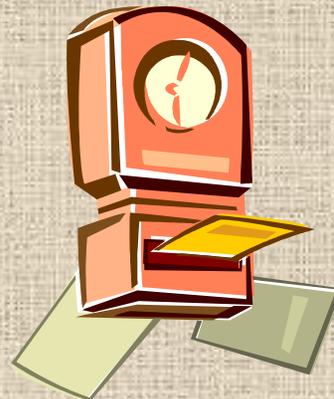
Albert is the key decision maker in an upcoming contract negotiation to determine which reference lab to use. The customer service representative from one of the labs in consideration tells him that he has two extra front-row tickets to tonight's Lakers' game and will just have to throw them away if Albert doesn't want them. What should Albert do?

Answer

Albert should politely decline the tickets as it is against policy to accept personal gifts of any substantial value. It may now be difficult for him to remain impartial in making the contract decision about the reference lab. He should seek further advice from his Manager or the Compliance Department.

Clocking In

Mary is on her way back from lunch and calls Jane at the lab and asks her to clock in for her since she is caught in traffic and has already been tardy a couple of times this month. They are “best friends.” What should Jane do?



Answer

- A. Ask Mary for her password and clock in for her so she doesn't lose her friendship.
- B. Tell Mary that she values her as a friend but can't do it because they will both be fired without question if anyone finds out as it is against the lab's compliance policy.
- C. Tell Mary she will do it and then conveniently "forget" to ask Mary how to log in for her
- D. Tell Mary "no" and then tell her co-workers that Mary is going to be late AGAIN



Overtime

Manny, the laboratory Senior Supervisor, is concerned about a recent productivity report which didn't meet expectations. He needs May to stay past the end of her shift because the blood gas machine has to be fixed. He asks May to clock out at her regular time but stay two more hours "off-the-clock" and tells her that he will make it up to her. What is the problem here?

Answer

It is understandable that Manny wants the productivity report for his section to look good, but he can't break the law and/or go against Medical Center policy to do so. He can defend the numbers on his next productivity report, but there will be no defense in court if May complains about having to work overtime without being paid.

Pizza Party

A representative from one of the major laboratory supply companies brings pizzas to the lab for lunch every Friday, but this welcome treat is not part of a continuing education session provided by his company. Everybody in the lab has access to the food. This is an acceptable practice.

Answer

- True
- False



Even though this does not qualify as a “personal gift”, it could inappropriately influence future decisions about which supply company to use.

Billing Inappropriately

The Laboratory Manager in Support Services is informed that Medicare has received a claim from the lab for a physician who has been excluded from Medicare. What should the Manager do?



Answer

The Manager can begin by pulling the original requisition and initiating an investigation. If it is determined that the physician in question was indeed excluded from Medicare at the time the order was placed, a refund must be sent immediately to Medicare along with a formal explanation. If the investigation reveals that there has been a mistake and the physician ordering the test was not excluded from Medicare at the time, a formal explanation is sent to Medicare and corrective action taken to ensure this does not continue to happen.

Cultural Dilemma

Sam is a fantastic phlebotomist and also knows how to put his patients at ease, especially kids. He has gotten to know Abdul well during his long stay at the Medical Center and has finally gotten him to stop fighting with him when he comes to draw his blood. Sam is nearby when Abdul's parents are getting ready to take him home. Abdul's father insists it is "his duty" to thank Sam for taking such good care of his family and thrusts \$10.00 into his hand. What should Sam do?



Answer

It is hard to know what to do when there is a conflict between the compliance policy and the cultural needs/beliefs of the patients or their families. Sam must not accept the money, but he needs to decline the offer in as sensitive a way as possible. He can call the UCLA Healthcare Ethics Center at extension 46219 for advice on this or other similar issues.

Conflict of Interest

The sponsor of a major clinical trial asks the physician who is conducting the trial to purchase their newest chemistry analyzer even though it is much more costly than that of the only major competitor. What should the physician do?



Answer

The physician should explain that he must follow the written protocol for selection of capital equipment or risk losing his appointment. The sponsor should be advised to put together a Request For Proposal (RFP) for the instrument to show why the physician should purchase it even though it is more expensive.

Proprietary Information

John is approached by a reagent manufacturer who is interested in a “home brew” test the lab has been using for an esoteric test that they would like to add to their test menu. He tells John that he will get a “consultant’s fee” if he shares information about the test protocol. What should John do?



Answer

- A. Tell the manufacturer that information about the test methodology is confidential as it is the “property” of UCLA.
- B. Give the manufacturer the information and accept the consultant’s fee.
- C. Tell his Supervisor about the situation and/or contact the Compliance Office.
- D. Both A and C are correct.



Kick Back

Tom is a Lab Manager and is approached by a sales representative from a small reference lab performing specialized testing who wants to give Tom more information about their services. The sales rep invites Tom to lunch and tells him that his lab is willing to hire Tom as a part-time consultant if he decides to start sending certain tests to them. Tom won't actually have to spend any time at the lab, just send the specimens. What should Tom do?

Answer

- A. Accept the consulting position as it will look good on his resume and extra income is always welcome.
- B. Tell the sales representative that he is not interested in the consulting position, but will be happy to look at literature about the reference lab – then consider that this reference laboratory may not be following the compliance requirements and would be dangerous to use.
- C. Angrily tell the sales representative that both he and his company must be crooked since they offer kickbacks to potential clients.
- D. Walk out without saying a word.

Lab Phlebotomist in MD Office

Joe works for Zeta Lab and has been assigned by them to provide phlebotomy services for one of their clients, Dr. Smith. Joe has taken both compliance and customer service training at Zeta Labs and isn't sure what to do when Dr. Smith asks him to help out in the file room when he isn't busy with a patient.

Answer

Joe should politely decline and let Dr. Smith know that it is a violation of Zeta lab's compliance policy and Federal Law for him to provide "free services" not directly connected with collection or processing of the specimens for Zeta Lab.



Free FTE

Jim is the Office Manager at Magnificent Lab and is shopping for new chemistry analyzers to replace the one the lab has outgrown. The customer service representative of one of the top vendors offers to provide him with a “free employee” as part of the contract. What should he do?



Answer

- A. An extra pair of hands is much needed at the lab and this offer sounds enticing enough to sway Jim to offer the contract to this vendor.
- B. Explain to the customer service representative that he won't be able to accept this particular offer because it is against his lab's compliance policy and negotiate for a lower reagent price instead – then continue with the normal capital equipment selection process taking into account that this vendor may be ethically “challenged” and/or has not properly trained its client service representatives.
- C. Report to both the vendor and the OIG that this client service representative has broken the law.
- D. Tell the client service representative that he is a crook.

Scope of Practice



Mary Beth runs the lab at a busy physician's office and is asked by Dr. Brown (who is also the Laboratory Director) to call Prothrombin Time results to patients and tell them to adjust their dosage if the results are too high or too low. Mary has listened to the doctor do this for years and knows exactly what he would do. What should Mary Beth tell Dr. Brown?

Answer

- A. Mary Beth should obey Dr. Brown's request and be proud that he trusts her.
- B. She should tell Dr. Brown that she can't help him with this because it is outside her scope of practice to "diagnose" and she doesn't know enough about each patient's history to make a fully informed decision.
- C. She should quit, since it is hard to refuse a direct request from the Laboratory Director.
- D. Mary Beth should buy the latest medical book about coagulation and study up before contacting patients and adjusting their dosage.

CPT Coding



Jill works in patient billing in a small office and is trying to find the right CPT code to use for a new test being offered in the laboratory. She can't find one that matches the test methodology the lab is using, but does find one for the same test by a more complicated method. What should she do?

Answer

- A. Use the code for the more complicated procedure, since there isn't one available for the procedure in use.
- B. Use the "unlisted test" code in that test category, e.g., chemistry, hematology, etc.
- C. Call the lab and tell them they can't perform the test because it can't be billed.
- D. Leave the charge for that test off the bill.



Laboratory Supplies

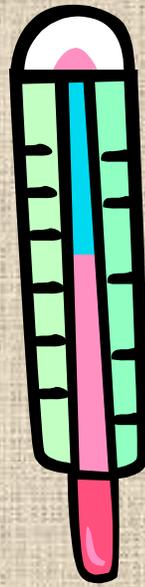
Zeke works at XYZ Lab in the Customer Service Department. He has noticed that Dr. Peter's office manager calls him at least once a week and orders a case of sterile urine collection cups but only sends in 2 urine specimens back in these containers in a month's time. What should Zeke do?

Answer

- A. Continue to send a case of sterile urine cups each month since he doesn't want XYZ Lab to lose a client.
- B. Report this to his Supervisor and ask him/her to help with this concern and get back to him with what is to be done.
- C. Tell Dr. Peter's Office Manager that he won't be able to send any more sterile urine cups because they should have enough to last for years.
- D. Ignore it as sterile urine cups aren't very expensive.

QC Compliance

George forgot to read the temperature log on the hematology refrigerator two days last week because he was late for work. The CAP inspection is coming up. What should he do?



Answer

- A. Write in temperatures that are close to the readings he normally gets so there won't be any gaps in the temperature chart when the CAP inspector comes.
- B. Note that the temperature was forgotten those two days on the corrective action log for the temperature chart and let his Supervisor know so appropriate corrective action can be initiated and recorded.
- C. Leave everything "as is" and explain to the CAP inspector what happened if they happen to ask.
- D. Complain that he is always the only one who reads the temperature logs and it should be a "shared" responsibility.

ICD-9 Coding

- Ann is a coder for the clinical lab and gets requisition without an ICD-9 diagnosis code from the referring MD. What should she do?



Answer

- A. Use the code that is in the system from the last visit.
- B. Look in the chart to see if there is a diagnosis code that was used previously that will ensure the test will be paid for by the insurance company.
- C. Contact the physician and ask for a diagnosis code for this encounter and ensure that this is sent in writing within 30 days.
- D. Put the requisition on the bottom of her “problem pile” and worry about it when she has more time.

Patient Courtesy



Mrs. O'Hara is 80 years old and comes in for her annual physical screening exam which is not covered by her Medicare insurance. She asks the person in charge of laboratory billing to include a diagnosis code (ICD-9 code) that her insurance will cover, because she cannot afford to pay for the tests herself. What should be done?

Answer

- A. The coder should tell Mrs. O'Hara that she cannot include a code that is not indicated by the provider for this visit, and that she should talk to her physician if she cannot pay for the tests he has ordered so they can work out the best solution together. Then arrange for her to meet with him before she goes.
- B. The coder should avoid any conflict with the patient and do what she says.
- C. The coder should tell Mrs. O'Hara that there is nothing that can be done about it and she will have to pay for the tests herself.
- D. The coder should "write off" the lab tests.

Medical Necessity

Pam is a CLS and works in a small lab in an Endocrinology Clinic connected to the Medical Center. The provider she works for orders a TSH on every single patient he sees every single time they come in. When she asks him why, he says that it is one test that gets good reimbursement and it's what allows him to give her a raise each year. What should Pam do?



Answer

- A. Forget about it and keep quiet, since she wants to keep getting her raises every year.
- B. If she is uncomfortable talking to the provider himself about the concern, she can call the UCLA Compliance Hotline at (800) 296-7188 or contact the Hospital Compliance Office (310) 825-7135 and ask for advice.
- C. Call the OIG and report that UCLA is billing fraudulently.
- D. Quit, since her boss is obviously more interested in the bottom line than his patients.

Upcoding

George notices that Medicare reimbursement for one of the chemistry tests performed in his lab is much higher for a method he doesn't use. He knows that money has been tight lately and decides to use the CPT code with the higher reimbursement when he bills Medicare for the test. What can happen?



Answer

Upcoding can lead to huge fines if an audit is ever performed and it is discovered. It can also lead to criminal charges, including jail time and the OIG can then require the laboratory to comply with a very rigid compliance plan and/or shut down.

Theft

Billy saw his co-worker Sue secretly stick a laboratory timer into her purse right before she left to go home. What should he do?

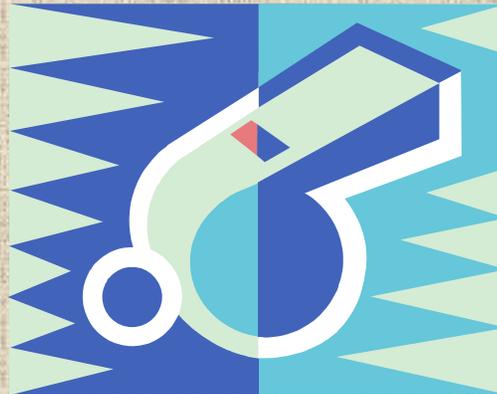


Answer

- A. Report the incident to his Supervisor.
- B. Call Security and tell them that Sue is a thief.
- C. Call the campus police and report the theft.
- D. Keep quiet, since it isn't right to "rat" on someone you know.

Whistle Blower

Shortly after Andrea brings a compliance concern to her Supervisor in hematology, she is disciplined for something that she never had been written up for before. What should she do?



Answer

- A. Contact the compliance office via the hotline or directly and report that she feels that there has been retaliation because of her report of a compliance problem in the lab.
- B. Confront her Supervisor and tell him/her that she is going to get them in trouble for what they have done.
- C. Accept what has happened and try hard not to repeat what she was written up for this time.
- D. Go over her Supervisor's head and report this to the Laboratory Director.