PHARMACY LAW:
WHAT TO EXPECT DURING AN INSPECTION
A Knowledge Based Course For Technicians

By

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Course Value: Two Contact Hours
Reading: 19 Pages
Final Exam: 20 Questions
Completion Requirements: Answer 70% of the questions correctly. Evaluation
Statement of Need

In order to determine whether pharmacies are complying with state and federal laws and regulations, administrative agencies have the authority to inspect pharmacies. Inspections may be routine and simply to confirm compliance with the law, or triggered by (1) a fear of an imminent danger to the public health, safety, and welfare; (2) a formal complaint; or (3) the belief that a specific violation has occurred or will occur.

While it is the pharmacist in charge who maintains most of the liability during an inspection; as a pharmacy technician it is important that you are aware of the laws surrounding an inspection so that you will not appear surprised by this inevitable part of pharmacy life.
Course Objectives

Upon successful completion of this activity:

1. Understand the Fourth Amendment and how it applies to a pharmacy setting.

2. Learn the new probable cause standards that are applied to pharmacy inspections.

3. Understand the type of inspections a pharmacy may be subject to and what to expect from each.

4. Lean some of the practical considerations when faced with an inspection.
**Introduction**

In order to determine whether pharmacies are complying with state and federal laws and regulations, administrative agencies have the authority to inspect pharmacies. Inspections may be routine and simply to confirm compliance with the law, or triggered by (1) a fear of an imminent danger to the public health, safety, and welfare; (2) a formal complaint; or (3) the belief that a specific violation has occurred or will occur.

While it is the pharmacist in charge who maintains most of the liability during an inspection; as a pharmacy technician it is important that you are aware of the laws surrounding an inspection so that you will not appear surprised by this inevitable part of pharmacy life.

**The Fourth Amendment**

Before we discuss the types of inspections and preparations for a pharmacy, it is important that we frame all U.S. laws within our constitution. The *Constitution of the United States of America* is the supreme law of the United States. The Constitution is the framework for the organization of the U.S. government and for the relationship of the federal government to the states, to citizens, and to all people within the United States.

The Fourth Amendment of the U.S. Constitution provides protection from an unreasonable governmental search in that it guarantees that “the right of the people to be secure in their persons, houses, papers, and effects, against unreasonable searches and seizures, shall not be violated, and no warrant shall issue, but upon probable cause, supported by oath or affirmation, and particularly describing the place to be searched, and the persons or things to be seized.”

The Fourth Amendment to the Constitution protects individuals from unreasonable searches and seizures. Search warrants are issued only to authorized law enforcement officers by judges. Law enforcement officers must be concerned that any search or seizure will withstand constitutional scrutiny. Under the “exclusionary rule,” no evidence obtained in a search can be the difference between winning or losing the case.

The Fourth Amendment has been characterized as “the one procedural safeguard in the Constitution that grew directly out of the events that immediately preceded the revolutionary struggle with England.” Prior to the Declaration of Independence, the British used a legal device called a “general warrant” to search the premises and products of colonial merchants and businessmen for noncompliance with Parliamentary revenue acts (notably the Stamp Act of 1765). The general warrant was issued on a whim; it was not necessary to support the application for the warrant with evidence that the revenue law was being violated. Equally irritating to the colonist was the “writ of assistance” document, which gave the King’s customs official’s power to search at large for smuggled goods.
Therefore, the framers of the Fourth Amendment were concerned with protection of both home and business from “unreasonable searches and seizures” and were concerned that “…no warrants shall issue, but upon probable cause…” Most court cases dealing with Fourth Amendment rights center around the application of the key provisions “unreasonable” and “probable cause.”

The Fourth Amendment has been the subject of many U.S. Supreme Court cases. The Court is often called upon to determine whether officers were entitled to seize evidence without a warrant, whether officers exceeded the scope of a warrant, and whether the probable cause used to justify a warrant was sufficient. The case law on these issues is extensive and somewhat complicated, even confusing. Some authorities find it unfair that law enforcement officers must make instantaneous decisions in the heat of a criminal investigation, and yet the courts have years to analyze whether the officers’ decisions were constitutional.

The safeguards of the Fourth Amendment applied only to criminal searches until 1967 when the U.S. Supreme Court extended Fourth Amendment protection to administrative inspections. Prior to 1967, the courts held the opinion that searches by administrative agencies were noncriminal in nature and that such searches represented only a minimal intrusion into personal privacy. The companion cases of See v. City of Seattle, 387 U.S. 541 (1967) and Camara v. Municipal Court, 387 U.S. 523 (1967) initiated a new era of judicial thinking in the area of governmental inspection. Based on the decisions in these two cases, a search warrant is required, as a general rule, when an administrative inspection is to be conducted, even if commercial premises like a pharmacy are involved. Justice White, writing for the Court in See v. City of Seattle, stated the following:

… a search of private houses is presumptively unreasonable if conducted without a warrant. The businessman, like the occupant of a residence, has a constitutional right to go about his business free from unreasonable official entries upon his private commercial property. The businessman, too, has that right placed in jeopardy, if the decision to enter and inspect for violation of regulatory laws can be made and enforced by the inspector in the field without official authority evidenced by a search warrant.

The protection accorded by the Camara and See cases was expanded by the U.S. Supreme Court with its 1978 decision in the case of Marshal v. Barlow’s Inc., 436 U.S. 307, where the Court had the opportunity to comment on the basic purpose of the Fourth Amendment:

… the Fourth Amendment prohibition against unreasonable searches protects against warrantless intrusions during civil as well as criminal investigations (citing See v. City of Seattle, 387 U.S. 541 [(1967)]. The reason is found in the “basic purpose of this Amendment… (which) is to safeguard the privacy and security of individuals against arbitrary invasions by governmental officials.”
The Barlow’s decision also reiterated the general rule that “… warrantless searches are generally unreasonable and this rule applies to commercial premises as well as home… Except in certain carefully defined classes of cases, a search of private property without proper consent is ‘unreasonable’ unless it has been authorized by a valid search warrant.” Constitutionally recognized rights, such as the requirement of a search warrant, must be balanced with the government’s duty to protect the public health, safety, and welfare. The courts have not had an easy time balancing these two basic considerations, and a number of exceptions have arisen from the general rule requiring a search warrant.

Probable Cause

Probable cause exists when the circumstances would convince a reasonable person to believe that a crime has been committed or that the property to be searched will contain items related to a criminal act.

Because of the nature of administrative inspection it has been difficult for courts to require the stringent probable cause standards of a criminal case. For example, it is highly unlikely that board of pharmacy inspectors, hoping to conduct a routine inspection of a pharmacy, would have evidence that a crime has been committed. One by-product of See v. City of Seattle is to use the terminology of Justice Clark, a “new-fangled warrant” in the form of the administrative inspection warrant. The inspection warrant differs from the traditional search warrant in that a judge or magistrate issues an inspection warrant merely upon application, with supporting affidavits showing that a substantial period of time has passed since the last inspection (United States v. Pendergast, 436 E.Supp. 931 [W.D.Pa. 1977]). In contrast, a traditional search warrant issued only on affidavits establishing probable cause that evidence of a crime will be found at the place to be searched.

The new probable cause standards have been applied to cases involving pharmacy inspections. In United States v. Anile, special agents of the Bureau of Narcotics and Dangerous Drugs (BNDD) (now called the Drug Enforcement Administration [DEA]) visited a West Virginia pharmacy to conduct an inspection. As a result of the inspection, the pharmacy owner was arrested because of discrepancies in the pharmacy’s controlled substance records. Although the case primarily focused on the voluntariness of the pharmacist’s consent to a warrantless search, the court also stated that “the standards that apply to administrative inspections are not, by their very nature, the same that apply to criminal searches and seizures.” (352 F. Supp.14 [N.D.W.Va. 1973]).

The legality of a pharmacy inspection under the Controlled Substance Act (CSA) was tested in United States v. Greenberg (334 F.Supp 364 [W.D.Pa. 1971]). The court reasoned that in the usual probable cause situation, the issuance of a warrant was supported with evidence that a crime had been committed, and that the premises to be inspected contained the fruits of the criminal act. The court noted that an inspection warrant under the CSA is different:
… We believe that in the absence of any evidence of the commission of some violation of the Act, a valid public interest in the enforcement of the Act could still be shown. For instance, there is a valid public interest in ensuring compliance with the record keeping requirements of the Act. To this end it would seem entirely proper to conduct an inspection of a particular premise simply because a substantial period of time had passed since the last inspection. In the sited case no inspection had ever been made of the premises in question.

Although the search warrant and the inspection warrant have some similarities it is important to recognize the difference in probable cause standards as described above.

Inspections without Warrants

A search warrant or administrative inspection warrant is not required in all instances: (1) If the search is incidental to a lawful arrest and is confined to an area in the immediate control of the arrestee; (2) in emergency situations presenting imminent danger to health and safety; (3) in exigent circumstances where immediate actions is needed to prevent removal or destruction of the evidence or to prevent danger to the inspectors; (4) when entry and inspection are limited to areas of commercial premises open to the public; (5) when the search is in an “open field,” when the inspector is in pursuit of an escaping suspect, or if the item sought is in plain view (provided that the inspector is legally in the place where he sees the item and its discovery is inadvertent); (6) in situations when the warrant is not constitutionally required as decided by the U.S. Supreme Court on a case-by-case basis; and (7) when consent to the search is freely, voluntarily, knowingly, and understandingly given.

The Camara and See cases required search warrants for administrative inspections, but there are a number of important exceptions to this requirement. The first significant case holding a warrantless inspection constitutional was Colonnade Catering v. United States, 397 U.S. 72 (1970), The case involved confiscated liquor and other evidence obtained by agents of the Federal Alcohol and Tobacco Tax Division during a search without a warrant. The agents were acting under the authority of a federal law that allowed such inspections in the liquor industry. The U. S. Supreme Court held the relevant statute valid because the liquor industry had a long history of “close (governmental) supervision and inspection.”

The Colonnade case set the stage for a number of case rulings interpreting the inspection provision applicable to pharmacies. In United States v. Business Builders Inc., 354 F.Supp. 141 (N.D.Okla. 1973), a federal court upheld warrantless inspections under Section 704 of the Federal Food, Drug and Cosmetic Act. The court indicated that consent to an inspection is immaterial because the inspection statute took the place of a valid search warrant.

A 1984 New Jersey trial court decision confirmed the state’s right to conduct warrantless administrative searches of a pharmacy. The pharmacist challenged the constitutionality of routine, unannounced inspections by the New Jersey Board of Pharmacy. The court
concluded that the pharmacist had no expectation of privacy because state statutes required a review of prescription records and included special rules for dispensing poisons and controlled substances. Furthermore, the pharmacy had been inspected 4 times in the last 3 years. The judge found it unrealistic to conclude that the owner had no expectations that the pharmacy would, from time to time, be inspected by government officials (Greenblatt v. New Jersey Board of Pharmacy, 518 A.2d 1116 [N.J. Super. App.Div 1986]).

Licensing Exception

The Colonnade decision gave rise to what has been termed the licensing exception to the general rule. This is also known at times as the “highly regulated industry” exception. These cases fall into the category of situations where warrants are not constitutionally required based on a case-by-case analysis by the U.S. Supreme Court. The licensing exception has been used by the courts in upholding warrantless searches of businesses and industries that are regulated heavily by the federal government.

Businesses with histories of close governmental regulation are subject to warrantless searches as long as the searches are specifically authorized by statutes limiting the time, place, and scope of the inspection. The courts have ruled that those businesses that are licensed and extensively regulated have few expectations of privacy; thus, judges have justified the creation of implied consent inasmuch as the licensee expects frequent inspections and give implied consent to a warrantless search when the license is granted.

The implied consent theory has been applied in some legal actions involving pharmacy inspections. In McKaba v. Board of Regents of the State of New York (294 N.Y.S. 2d 382 [1968]), a pharmacist failure to object to a warrantless inspection raised questions regarding the admissibility of the evidence obtained. The court stated, “In accepting his license, the petitioner accepted the incident obligation of keeping the required records and permitting their inspection. The dangers and hazards of narcotics to health and public safety are known to all. Such records are not privileged records required by statute to be kept for proper regulation and protection of the general public, and their inspection without a search warrant was constitutionally valid.”

Types of Inspections

DEA Inspections

They type of inspection often feared by pharmacies is the Drug Enforcement Administration (DEA) inspection, in particular the drug accountability audit. The Controlled Substance Act provides that the DEA may enter and inspect any place where controlled substance records are kept or persons are registered under the CSA (21 U.S.C. 880; 23 C.F.R. 1316.01 – 1316.13). Under the CSA, a DEA inspector is allowed to examine and copy all records and reports, to inspect the premises within reasonable limits, and to take an inventory of the controlled substances. Unless the owner or pharmacist in charge consents in writing, the inspector is not allowed to inspect financial
data, sales data other than shipment data, or pricing data. In a normal audit, the inspector examines the records of the amount of drug(s) received and the records of the amount of drug(s) dispersed. The inventory should account for the difference in these amounts. Inspectors also examine records to determine their legitimacy, accuracy, and compliance within the law.

If the audit shows substantial discrepancies, the involved pharmacist may be charged with illegally distributing controlled drugs, failing to keep and maintain controlled drug records, or furnishing false information in such records.

The accountability audit inspection is not limited to the DEA. In some states, a state authority has the power, under the Uniform State Controlled Substance Act, to conduct this type of pharmacy inspection. The state inspectors or DEA compliance investigators may come armed with an administrative inspection warrant issued by a magistrate or judge. An audit may be conducted pursuant to “voluntary consent,” and the DEA Notice of Inspection (Form DEA-82) provides for such. However, the courts sometimes find that the consent is not voluntary especially if prescriptions or other records are seized by the inspectors (United States v. Pugh, 417 F.Supp. 1019 [W.D.Mich. 1976]).

An accountability audit made pursuant to an administrative inspection warrant was upheld as valid in United States v. Schiffman, 572 F.2d 1137 (5th Cir. 1978) and in United States v. Pendergast, 436 F.Supp. 931 (W.D.Pa 1977). In the Schiffman case, the pharmacist argued that there was no “probable cause” to support the issuance of the warrant. The court held that large purchases of controlled substances by a pharmacy were enough to create a valid public interest or probable cause to issue an administrative warrant.

Before an inspection, the inspector is required to state the purpose of the inspection and present to the owner or pharmacist in charge the agent’s credentials and a written notice of inspection. The notice contains the name of the owner or pharmacist in charge, the name and address of the business, the date and time of the inspection, and a statement that the notice has been given.

Consent Requirements

In addition, the inspector must obtain a written statement of informed consent to the search, signed by the owner or pharmacist in charge. The statement must note that the owner or pharmacist in charge has been informed of and understands the following:

- There is a constitutional right to refuse the inspection until an administrative inspection warrant has been obtained.
- Any incriminating evidence found may be seized and used against the owner or pharmacist in charge in a criminal prosecution.
- A notice of inspection has been presented.
- The consent is voluntary and not coerced.
- The consent may be withdrawn at any time during the course of inspection.
The written consent must be produced in duplicate; the inspector keeps the original and gives the copy to the person who consented to the inspection.

Courts have addressed the issue of whether a pharmacist’s consent is voluntary or coerced. In *United States v. Enserro*, 401 F. Supp. 460 (W.D.N.Y. 1975), DEA officers responded to a complaint about the illegal distribution of drugs at the defendant’s pharmacy. With a notice of inspection in hand, the agents approached the employee-pharmacist on duty and showed him a copy. They told the pharmacist that he “would face criminal penalties under Title 21 of the United States Code unless he signed a consent permitting the inspection.” (401 F.Supp.462). Faced with that threat, the pharmacist signed the consent and permitted the inspection. The owner-defendant was subsequently charged with the illegal distribution of schedule II controlled substances, but the court found that the evidence had been obtained illegally because the consent was forced.

Rather than giving unconditional consent, the owner or pharmacist in charge may wish to give a limited consent, specifically excluding a particular part of the premises or particular records. The owner or pharmacist in charge should then document the limited nature of the consent in writing and the documentation should be signed by both parties.

**State Pharmacy Board Inspections**

The most common governmental intrusion into the pharmacy is the periodic visit by the pharmacy board inspector. Usually, the inspection is not traumatic and is routine; it is more educational than investigative. The inspector will check pharmacy compliance with the laws and regulations pertaining to pharmacy staffing, sanitary conditions, and professional equipment, as well as perhaps compliance with mandatory continuing education requirements of the state. The State Pharmacy Act may well contain a provision similar to that found in the Model Pharmacy Act promulgated by the National Association of Boards of pharmacy:

The Board of Pharmacy shall be responsible for the control and regulations of the practice of pharmacy in this state, including but not limited to, the following:

Inspection of any licensed person and appropriate records at all reasonable hours for the purpose of determining if any provisions of the law governing the legal distribution of drugs or devices or the practice of pharmacy are being violated. The Board of Pharmacy, its officers, inspectors, and representatives shall cooperate with all agencies charged with enforcement of the laws of the United States, of this state, and of all other states relating to drugs devices, and practice of pharmacy (213[a][12]).

Most pharmacists freely consent to the state board inspection, unless a personality clash arises between the pharmacist and the inspector. Although this type of inspection is
usually harmless, the pharmacist should be aware of a situation where the inspection becomes a search for incriminating evidence.

State boards of pharmacy and the DEA often work collaboratively when controlled substances are the subject of a pharmacy investigation. The requirements of the CSA applicable to DEA inspectors do not apply to state board inspectors. Rather, state law dictates the procedures they must follow.

Unlike the federal CSA, some state laws allow the inspection of pharmacies without warrants

Food and Drug Administration Inspections

Food and Drug Administration (FDA) inspections of pharmacies are rare. This is because the Federal Food, Drug, and Cosmetic Act (FDCA) contain an exemption from the authorization given to the FDA to conduct inspections as follows:

Pharmacies which maintain establishments in conformance with any applicable local laws regulating the practice of pharmacy and medicine and which are regularly engaged in dispensing prescriptions drugs or devices, upon prescriptions of practitioners in the course of the professional practice, and which do not, either through a subsidiary or otherwise, manufacture, prepare, propagate, compound, or process drugs or devices for sale other than the regular course of their business of dispensing or selling drugs or devices at retail (21 U.S.C. 364[a][2][A]).

Usually the FDA agent only calls at the pharmacy to inquire about or look for the presence of a recalled drug or drug banned from the market. The FDA might inspect a pharmacy on the basis of some complaint lodged with the agency on the basis of Prescription Drug Marketing Act investigations involving alleged sales of samples or the investigation of pharmacies engaged in manufacturing or repackaging. In case of the last situation, the FDA will be inspecting the pharmacy’s operation as it relates to good manufacturing practices requirements.

The FDA apparently has taken the position that its inspections fall within the boundaries of those cases that permit warrantless searches of heavily regulated businesses. It is felt that there is little expectation of privacy by those who deal with food and drugs. The statutory limitations of the time, manner, and scope of FDA inspections fit in well with the dictates of the cases espousing the implied consent or licensing exception.

**Practical Considerations**

When an agent or inspector visits the pharmacy for an inspection, the pharmacist should ascertain the purpose of the inspection and not the agent’s credentials. Under normal circumstances pharmacists should not fear an inspection, especially if it is a routine state board inspection, and should be cordial and cooperative. If the inspection is not routine and is for the purpose of conducting a controlled substance accountability audit, the
pharmacist should contact the employer or supervisor, who may wish to contact an attorney. If the inspector has an administrative inspection warrant, the pharmacist should never refuse to allow the agent to inspect. If the inspector does not have an administrative inspection warrant, the pharmacist must decide whether to consent to the inspection or not depending upon the circumstances. Remember, in some states board inspectors do not need a warrant and consent would not be needed. If the pharmacist denies consent but the agent insists on inspecting anyway, the pharmacist should document the conversation, obtain the agent’s signature, and allow the agent to inspect. Resistance or interference could lead to arrest. The validity of the search would be determined at a later time.

Never lie to an agent, and generally the best course of action is to say as little as possible if the inspection is routine. Also, for other than routine board inspections, the pharmacist should document what is said and done during the inspection. In addition, as a technician, you should not sign anything presented by an agent.

A DEA Notice of Inspection (Form DEA-82) is not an administrative inspection warrant. If an FDA agent presents Form FD-482, he or she is entitled to entry and inspection because the FDA notice takes the place of the administrative inspection warrant if the inspection is limited in scope. If the FDA agent wants to conduct an accountability audit of a pharmacy he or she probably will need to an administrative inspection warrant (and the pharmacy could insist on such) because the authorizing law (704 of the FDCA) limits the scope of pharmacy inspections. If the agent has no administrative inspection warrant but insist on conducting a drug accountability audit, the pharmacist should not resist. The audit should be submitted to after first asserting a demand for the administrative inspection warrant.

The U.S. Supreme Court in United States v. DiRe (332 U.S. 581 [1947]) stated,

Courts will hardly penalize failure to display a spirit of resistance or to hold futile debates on legal issues…with officers of the law. A layman may not find it expedient to hazard resistance on his own judgment of the law at a time when he cannot know what information, correct or incorrect, the officers may be acting upon… It is the right of (any) one…to reserve his defense for the neutral tribunals erected by the law for the purpose of judging his case.

If an inspector announces that this is an administrative inspection or has search warrant but will not present it, the pharmacist should yield and allow entry and inspection. However, the pharmacist in charge may assert that the inspection is being allowed under protest.

Refusal to permit execution of an administrative inspection warrant or to impede the inspection in the execution of the same violates 402(a) (6) of the CSA and may lead to the arrest of the violator.
No one in the pharmacy should interfere with the inspection, audit, or seizure of records or prescriptions. If items are seized, a copy of the warrant will be left. Again, it is sufficient to state verbally to the agent that the inspection is allowed under protest and upon reliance that the administrative inspection warrant is valid.

An inspection or search can be contested later in a court action for emergency injunction quashing the warrant and suppressing any seized evidence (see *Weyerhaeuser v. Marshall*, 452 F.Supp. 1375[E.D.Wisc. 1978]).

If the agent asks questions or the audit shows substantial discrepancies, the agent must be shown where drug records are kept; otherwise, the search could extend throughout the premises. However, specific compliance questions or explanations of audit shortages and overages should be referred to a conference when the pharmacist’s attorney is present. It is better that an individual remain silent than to lie to the inspector. A lie to a federal officer in the course of an investigation could violate 18 U.S.C 1001. The employee or owner has the right to refuse to answer questions; however, any answers given can be held against the person if the agent has given the Miranda warning (explained in the next section). A lie to a state official conducting an investigation can be a crime of obstructing justice under applicable state law.

Silence is preferable to incriminating statements even if the statements are inadmissible in court. Once the secret is out the inspectors know what they are looking for. In *United States v. Bayer*, 331 U.S. 532 (1947), the court said...“after the accused has once let the cat out of the bag...he can never get the cat back into the bag. The secret is out for good.”

The old rule that silence is an admission of guilt no longer applies. An individual’s silence during interrogation cannot be used against him or her (*United States v. Hale*, 422 U.S. 171 [1975]).

It is important to make written notes of everything said or done by the agent during the inspection. If you are not a party to the conversation (by executing the right to silence), it cannot be recorded without permission, and the agent is not likely to give permission. Additionally, a tape recording will not pick up all of the activity. Written observations of the events will provide an accurate picture if it is needed later.

It is not necessary to sign anything without first conferring with an attorney. A receipt for drug samples taken by the FDA or a receipt for a state board inspection report are exceptions to the above; however, it is advisable that an individual be wary of signing anything that looks like a waiver of rights. In one case, a defendant signed a government agent’s prepared statement of facts, which amounted to an admission of guilt. The confession was allowed in court because the court felt that the defendant had ample opportunity to seek a lawyer’s advice before signing the statement.
Miranda Warning

In *Miranda v. Arizona*, 384 U.S. 436 (1966), the U.S. Supreme Court laid down the rule that under the Fifth Amendment a law enforcement officer’s custodial interrogation of an accused individual must be preceded by the following warning:

- The accused or person in custodial interrogation has a right to remain silent.
- Any statement that the accused makes can be used against them.
- The accused has the right to have a lawyer present before he or she is questioned.
- If the accused cannot afford to hire a lawyer, a lawyer will be provided for him or her at the expense of the government.

The Miranda warning when given is given either orally, in writing or both. It is addressed to the accused in the second person (e.g. “You have the right to remain silent.”); the people receiving the warning then may either waive their rights or refuse to waive them.

What is “custodial interrogation”? The courts are not in complete agreement on the meaning of this term. In the Miranda case, the court said that custodial interrogation is “…questioning initiated by law enforcement officers after a person has been taken into custody or otherwise deprived of his freedom of action in any significant way.” A number of federal courts have defined the term as meaning the time when the accused becomes the focus of a criminal investigation.

In general, the Miranda warning is not applicable to a pharmacy inspection. In a pharmacy inspection, the pharmacists and technicians are not in custody. They are free to depart if necessary; they may close the pharmacy for the day and leave. If the inspector is focusing on a pharmacist or technician as a suspect, the inspector often will give the Miranda warning; the warning may be required even if the suspect is being questioned in the investigator’s office, if the suspect is not free to leave (*Beckwith v U.S.*, 425 U.S. 341 [1976]).

The importance of the Miranda warning can be exemplified by a pharmacy inspection case, *United States v. Goldfine*, 538 F.2d 815 (9th Cir. 1976). During the course of an investigation, a DEA compliance investigator, after giving the Miranda warning, asked the pharmacist if he made any out-of-state purchases. The pharmacist stated that he had not. The answer proved false, and the pharmacist was convicted of violating a federal law (18 U.S.C. 1001) because of his false answer. In *Goldfine*, the court pointed out that the accused can say nothing or plead the Fifth Amendment, and either action cannot be used against him. However, in this case, the DEA investigator took the precaution of giving the warning, and the accused pharmacist apparently failed to heed it. The pharmacist waived his right by answering the questions, and giving a false answer to a federal official opened him to criminal prosecution.
**Conclusion**

For the most part, inspections are routine part of the pharmacy business. They are important to public safety and normally not stressful. The pharmacy board inspectors will usually show only their credentials and state their purpose when making a routine inspection. They may ask permission to enter and inspect, unless consent to the inspection is obvious, as in cases of initial inspections on applications for new pharmacy permits. Sometimes the board inspector will leave a copy of a report indicating items in need of correction or improvement and may ask the pharmacist in charge to sign for receipt of the report.
Final Exam

1. In order to determine whether pharmacies are complying with state and federal laws and regulations, administrative agencies have the authority to inspect pharmacies.
   a. True
   b. False

2. The Second Amendment of the U.S. Constitution protects individuals from unreasonable searches and seizures.
   a. True
   b. False

3. The Fourth Amendment is often called upon to determine whether officers were:
   a. Entitled to seize evidence without a warrant
   b. Whether officers exceeded the scope of a warrant
   c. Whether the probable cause used to justify the warrant was sufficient
   d. All of the above

4. The safeguards of the Fourth Amendment applied only to criminal searches until 1967.
   a. True
   b. False

5. Based on the decisions of _________ a search warrant is required, as a general rule, when an administrative inspection is to be conducted.
   a. See v. City of Seattle
   b. Camara v. Municipal Court
   c. Both a and b
   d. None of the above

6. Probable cause exists when the circumstances would convince a reasonable person to believe that a crime has been committed or that the property to be searched will contain items related to a criminal act.
   a. True
   b. False
Final Exam

7. The legality of a pharmacy inspection under the Controlled Substance Act (CSA) was tested in:
   a.  
   b.  
   c.  
   d.  

8. Both search warrants and inspections warrants have the same probable cause standard.
   a. True
   b. False

9. A search warrant or administrative warrant is required in all instances.
   a. True
   b. False

10. The ________ case set the stage for a number of case rulings interpreting the inspection provision applicable to pharmacies.
    a.  
    b.  
    c.  
    d.  

11. A _____ New Jersey trial court decision confirmed the state’s right to conduct warrantless administrative searches of a pharmacy.
    a. 1867
    b. 1908
    c. 1984
    d. 1978

12. The Colonnade decision gave rise to what has been termed the ________ .
    a. Licensing exception
    b. Implied consent
    c. Probable cause
    d. Inspection provision
Final Exam

13. The Controlled Substance Act provides that the DEA may enter and inspect any place where controlled substance records are kept.
   a. True
   b. False

14. The accountability audit inspection is limited strictly to the DEA.
   a. True
   b. False

15. An accountability audit made pursuant to an administrative inspection warrant was upheld as valid in ________________.
   a. *United States v. Schiffman*
   b. *United States v. Pugh*
   c. *See v. City of Seattle*
   d. *United States v. Enserro*

16. In __________ the issue of whether a pharmacist’s consent was voluntary or coerced was addressed.
   a. *United States v. Schiffman*
   b. *United States v. Pugh*
   c. *See v. City of Seattle*
   d. *United States v. Enserro*

17. The most common governmental intrusion into the pharmacy is the periodic visit by the pharmacy board inspector.
   a. True
   b. False

18. The statutory limitations of the time, manner, and scope of FDA inspections do NOT fit in well with the dictates of the cases espousing the implied consent or licensing exception.
   a. True
   b. False
Final Exam

19. If the pharmacist denies consent but the agent insists on inspecting anyway:
   a. The pharmacist should document the conversation
   b. Obtain the agent’s signature
   c. Allow the agent to inspect anyway
   d. All of the above

20. No one in the pharmacy should interfere with the inspection, audit, or seizure of records or prescriptions.
   a. True
   b. False