



# Healthcare Law Compliance Policies

 Compliance Hotline:  
1-877-PURDUE1 (1-877-787-3831)

Purdue Pharma L.P. and  
Associated U.S. Companies

Dear Colleagues,

Purdue (the Company) is committed to complying with all applicable laws and regulations governing our business and our products. Purdue also supports and subscribes to the PhRMA Code on Interactions with Healthcare Professionals. With these commitments in mind, Purdue employees are responsible for conducting business in conformance with these Healthcare Law Compliance Policies and Purdue's Code of Business Ethics (the Code). Employees are expected to read, understand, and abide by all of these policies, the Code, and other relevant policies and procedures.

These Healthcare Law Compliance Policies address the laws and regulations of the Food and Drug Administration (FDA), Centers for Medicare and Medicaid Services (CMS), and other healthcare regulatory agencies, and are enforceable by criminal, civil, and administrative penalties. Violations may result in jail sentences, fines, or exclusion from Federal and State healthcare programs, such as Medicare and Medicaid.

Each Purdue colleague has a critical role to play in the lawful and ethical conduct of our business. We want all colleagues to take the time to understand the principles behind the laws and regulations that underlie these important Company policies, so that we all will be aware of conduct that is lawful and appropriate. These policies are so important to Purdue that adherence to them will be considered in connection with all employee performance evaluations.

If you ever have questions about the operation of these policies, or have concerns about known or suspected violations of these policies, we expect you to raise them with your supervisor, a Business Partner in Human Resources, an attorney in the Law Department, a member of the Corporate Compliance Department, or via Purdue's Ethics and Compliance Hotline at 1-877-PURDUE1 (or 1-877-787-3831). Calls to the Hotline may be made anonymously. Purdue will not retaliate against any employee for good faith reporting of suspected violations or for raising a compliance or ethics issue. To the extent possible and appropriate under the circumstances, Purdue will attempt to honor an individual's request to keep such reports confidential.

Compliance with Purdue's Code and Healthcare Law Compliance Policies – along with relevant policies and procedures – has never been more important than it is now. We are counting on you to abide by these policies and to strive to do the right thing.

Thank you for your continued support and commitment to Purdue.



Maggie Feltz  
Vice President, Ethics & Compliance

The policies in this publication apply to the following Purdue associated U.S. companies (Company), as appropriate:

Pharmaceutical Research Associates, Inc.	Purdue Pharma Manufacturing L.P.	Purdue Pharmaceuticals L.P.
PharmIT Inc.	Purdue Pharma Products L.P.	Purdue Products Inc.
PharmIT L.P.	Purdue Pharma Technologies Inc.	Purdue Products L.P.
Purdue Pharma Inc.	Purdue Pharma of Puerto Rico	Purdue Transdermal Technologies L.P.
Purdue Pharma L.P.	Purdue Pharmaceutical Products Inc.	The P.F. Laboratories, Inc.
Purdue Pharma Manufacturing Inc.	Purdue Pharmaceutical Products L.P.	

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# KEY HEALTHCARE LAWS

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**There are many government enforcement agencies and numerous healthcare laws that regulate the pharmaceutical industry. Purdue expects all employees to have a basic understanding of the regulatory environment in which we operate. Brief descriptions of some of the key agencies and the laws they enforce are below.**

**Food and Drug Administration (FDA)**

The FDA has wide-ranging authority to regulate drug approval, safety, clinical studies, and product labeling, as well as advertising and promotion for prescription drugs. It also has at its disposal a host of enforcement tools, including regulatory “Warning Letters,” product seizure, import and export restriction, and monetary fines.

**Centers for Medicare and Medicaid Services (CMS)**

The CMS administers the Medicare and Medicaid programs. Medicare is a federal program that provides healthcare coverage for the elderly, disabled, and persons with end-stage renal disease. Medicaid, which is jointly funded by the federal government and the states and is administered by the states, is a healthcare program for people with limited income and resources. Both Medicare and Medicaid reimburse for certain pharmaceutical products.

**Other Government Agencies**

There are other agencies of the federal government that investigate healthcare fraud, such as the Department of Justice (DOJ), Department of Health and Human Services’ Office of Inspector General (OIG), Drug Enforcement Administration, Federal Bureau of Investigation (FBI), Department of Defense (DOD), and Department of Veterans Affairs (VA). In addition, almost every state has a Medicaid Fraud Control Unit and/or a state Medicaid Inspector General to investigate Medicaid issues, and the office of a state attorney general to look into any suspected violation of state law.

**The key health regulatory laws that form the basis for the policies set forth in this manual are:**

- The Federal Healthcare Anti-Kickback Statute
- The Federal Civil False Claims Act
- The Federal Food, Drug, and Cosmetic Act
- The Civil Monetary Penalties Law
- Federal Price Reporting Laws (including Medicaid Drug Rebate Statute, Public Health Services Act, and Veterans Health Care Act)
- The Health Insurance Portability and Accountability Act of 1996
- The Medicare Drug, Improvement, and Modernization Act of 2003
- The Physician Payments Sunshine Act (part of the healthcare reform legislation in the Patient Protection and Affordable Care Act of 2010)



## FEDERAL HEALTHCARE ANTI-KICKBACK STATUTE

### Relevant Purpose

The Federal Anti-Kickback Statute generally prevents companies such as Purdue from encouraging customers, directly or indirectly, to recommend, prescribe, or purchase Purdue products based on a financial incentive or “kickback” rather than sound medical judgment.

### Summary of the Law

As it applies to Purdue, the Anti-Kickback Statute generally makes it illegal to directly or indirectly offer or pay any “remuneration” to any entity (including vendors, customers, and potential customers) to induce that entity to recommend, prescribe, or purchase Purdue products when those products are being paid for by the federal government. “Remuneration” can be anything of value, such as discounts, rebates, grants, vouchers, cash, gifts, services, coupons, lottery tickets, trips, or free products. The government may view remuneration as a kickback *even if* one among many other appropriate reasons you provided it was to encourage your customer to prescribe or order Purdue products.

Similarly, the Anti-Kickback Statute generally makes it illegal for Purdue’s customers and vendors to accept any improper remuneration in exchange for prescribing or influencing prescribing of Purdue products. Thus, there is a common interest between Purdue and those individuals and entities with whom we do business to avoid an arrangement that might appear to be a “kickback.”

### “Safe Harbors”

Not all discounts, grants, and gifts are illegal. The government has established “safe harbors” to protect certain conduct. If a manufacturer fully complies with a safe harbor, it will not be liable under the Anti-Kickback Statute. Four safe harbors are particularly significant to pharmaceutical manufacturers:

- The Discount Safe Harbor protects certain price reductions, provided they are set in advance and properly disclosed and reported to the government
- The Personal Services Safe Harbor allows a manufacturer to enter into contracts with healthcare professionals for services such as speaking engagements, consultancies, and advisory boards. It is important to note that this safe harbor requires that the services be “bona fide” and that any fees paid for such services represent the “fair market value” for such services
- The Group Purchasing Organization (GPO) Safe Harbor protects certain administrative fees paid to GPOs

- The Managed Care Safe Harbor protects certain discount arrangements with managed care organizations

The specifics of these safe harbors are extremely complex. For this reason, all arrangements and contracts for the sale of Purdue products, including any discounts or rebate arrangements, as well as all arrangements for paid services, must be approved by the Law Department.

### Penalties

It is a felony to violate the Anti-Kickback Statute. Violators may be fined substantial penalties for violations, and may also face probation (for organizations) or prison (for individuals). Additionally, violation of the Anti-Kickback Statute may result in exclusion from the federal health-care programs such as Medicare and Medicaid. For Purdue, exclusion could mean that our products would no longer be reimbursed by these important federal payors. Likewise, there are state-based anti-kickback statutes under which Purdue could face penalties for activities deemed to be kickbacks.

Purdue employees may not offer anything of value to any individual or entity in order to increase the sales, prescribing, or formulary status of a Purdue product, except as may be explicitly permitted under all relevant Purdue policies and approved by the Law Department.



## FEDERAL CIVIL FALSE CLAIMS ACT

### Relevant Purpose

The government relies on certain information provided by pharmaceutical manufacturers in determining whether and what to pay for certain products and services under programs such as Medicare and Medicaid. The purpose of the Federal False Claims Act is to prevent the government from paying more than it should for a product or service because of false or inaccurate information.

### Summary of the Law

It is illegal to make – or assist others in making – false statements or claims to the government. A claim is “false” if the person or company making the claim actually knows that it is false or acts in “deliberate ignorance” of, or with “reckless disregard” for, whether the statement or claim is actually true. Under the False Claims Act, individuals with knowledge of false claims, sometimes called “whistle-blowers,” may bring suit on behalf of the government in so-called *qui tam* actions.

Unintentional or honest mistakes are not generally illegal. However, too many “honest mistakes” may suggest that a person or company is not taking care with the information it provides to the government and which could be viewed as “reckless disregard” of the truth.

If government reimbursement (including but not limited to Medicare or Medicaid reimbursement) for Purdue products depends on information that Purdue generates or reports, and Purdue “knowingly” fails to generate or report such information completely and accurately, or even is negligent in doing so, Purdue may be liable under the False Claims Act.

The following are some other examples of activities that the government may view as false claims:

- Failing to include the value of discounts and rebates (including “off-invoice” discounts) in certain prices reported to the government
- Providing “false invoices” to customers to assist them in obtaining a larger government reimbursement than they deserve
- Failing to correct the fact that a price provided to the government is clearly inaccurate
- Making inadequate efforts to check the accuracy of the prices submitted to the government
- Allowing employees with insufficient training and supervision to calculate prices reported to the government

- Encouraging a customer to bill inappropriately for a Purdue product, or
- Providing false product information or kickbacks (as described in more detail in other sections of these policies) to formulary committee members or prescribers in order to get Purdue products reimbursed by a federal healthcare program

### Penalties

Financial penalties for violations of the False Claims Act can be substantial. Moreover, there are other similar state and federal laws that would criminalize certain false claims. Additionally, violation of the False Claims Act may result in exclusion from federal healthcare programs such as Medicare and Medicaid. For Purdue, exclusion could mean that our products would no longer be reimbursed by these important federal payors.

In addition to the government, private insurers may rely on information developed by Purdue in making reimbursement decisions. Purdue employees, contractors, and agents shall not provide false information to any individual or entity, whether public or private.



## FEDERAL FOOD, DRUG, AND COSMETIC ACT

### Relevant Purpose

The ultimate purpose of the Federal Food, Drug, and Cosmetic Act (FDCA) is to protect consumer health. Under the FDCA, the Food and Drug Administration (FDA) regulates several areas of prescription drug development and marketing, including clinical studies, manufacturing, market approval, safety and efficacy, and advertising and promotion.

### Summary of the Law

In order to ensure that any drugs placed on the market are safe and effective, the FDCA requires clinical investigation of a new drug for a particular use. Clinical studies must be designed and conducted in compliance with applicable industry standards and in such a way as to produce scientifically accurate data. The FDA may only approve a drug that has been shown to be safe and effective for the use investigated during its clinical trial(s). Purdue may not promote a drug that is currently under clinical investigation. There are limited exceptions to disseminate information concerning a drug before it has received marketing approval from the FDA. These exceptions must be approved in advance by an attorney in the Law Department.

Even after a Purdue drug receives approval, the Company must control how its drug is promoted. A manufacturer may only promote a drug for its approved use, even though prescribers may use their professional judgment in determining how to prescribe the drug. Promoting a drug for an unapproved use is known as “off-label promotion,” meaning that the manufacturer is promoting the drug for a use not indicated in the drug’s approved labeling.

A drug’s “labeling” includes all information contained on its label, packaging, and its full prescribing information (FPI) or package insert (PI), as well as any other materials distributed by the manufacturer about the drug, and oral statements about the drug’s intended use. Thus, all such materials and statements must contain only information related to the drug’s approved use(s) as set forth in the FPI. As previously mentioned, there are some narrow exceptions to the off-label promotion rule, which can be used only when approved by Purdue’s Law Department.

In addition to promoting a drug only for its approved use(s), Purdue must promote its drugs in a way that is truthful and not misleading and that gives a “fair and balanced” description of the drugs’ risks and benefits. This means that risk information must be presented with prominence and

readability comparable to any safety or efficacy information. Fair balance must exist in our printed materials as well as any oral communications of a promotional nature.

The Prescription Drug Marketing Act (PDMA), part of the FDCA, regulates the distribution of prescription drugs. Under the PDMA, manufacturers must closely track the distribution of prescription drugs, including drug samples. Manufacturers are also prohibited from engaging in any sale of drug samples.

### Penalties

Violations of the FDCA, including violations of the PDMA, may result in civil penalties, such as monetary fines or criminal sanctions, including imprisonment. In order to monitor a manufacturer’s development and marketing of its drugs, FDA uses a variety of enforcement mechanisms. Such mechanisms may include conducting on-site facility inspections to ensure compliance with Good Manufacturing Practice and Quality Systems regulations, issuing “Warning Letters” or “Untitled Letters” if any deficiencies or regulatory violations are found with respect to product manufacturing or promotion, seizing products or withdrawing products from the market, and debarring individuals or companies from drug manufacturing or other FDA-regulated activities.



## FEDERAL PRICE REPORTING LAWS

### Relevant Purpose

State and federal laws (including the Medicaid Drug Rebate Statute, Public Health Services Act, Veterans Health Care Act, and Medicare Modernization Act (MMA)) require Purdue to report drug prices on a regular basis as a condition of its drugs being covered by various government reimbursement programs (such as Medicaid).

### Summary of the Law

There are complex rules governing the calculation of the pricing metrics that need to be reported to the government. Among other things, the following arrangements must, at a minimum, be considered by Finance and the Commercial Organization when reporting prices to the government: discounts (regardless of how they are noted or characterized), rebates, any price concessions, fees, credits, settlements of accounts receivables, provision of free goods contingent upon a sale of Purdue products, reduced-price services, or grants intended to lower the price of a drug.

### Penalties

Reporting inaccurate pricing information can lead to various civil and criminal penalties under the relevant laws. For example, penalties may be available under the Federal Civil False Claims Act, discussed in greater detail above. Additionally, penalties may be imposed under the government price reporting statutes themselves, and such penalties may include monetary fines, as well as potential criminal liability. Finally, Purdue's products may be excluded from coverage under most federal and state healthcare programs for violation of these price reporting laws.

Discounts, rebates, and other requests to lower the ultimate price of a Purdue product to a customer must be approved by the Senior Vice President and Chief Commercial Officer with the concurrence of an attorney in the Law Department.

## CIVIL MONETARY PENALTIES LAW

### Relevant Purpose

The Civil Monetary Penalties Law provides the OIG with the authority to impose civil monetary penalties (CMPs) for various activities involving the federal healthcare programs. These penalties are in addition to those penalties that might be available under other federal statutes, such as those discussed previously.

### Summary of the Law

The Civil Monetary Penalties Law provides for the imposition of CMPs against any person (including an organization or other entity) for various activities, including:

- knowingly presenting, or causing to be presented, false or improper claims to a state or federal government employee or agent
- violating the Federal Healthcare Anti-Kickback Statute
- engaging in certain arrangements or contracts with entities or individuals who have been excluded from participation in federal healthcare programs, and
- providing certain financial incentives or inducements to individual beneficiaries of federal healthcare programs

### Penalties

CMPs are civil fines that can be imposed in addition to any civil or criminal liability under the other laws discussed in these policies.



## HIPAA—PRIVACY OF MEDICAL INFORMATION

### Relevant Purpose

The purpose of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) is to protect personal health information from disclosure to unauthorized persons.

### Summary of the Law

HIPAA requires certain companies (known as Covered Entities) to take precautions when using or disclosing confidential health information under certain circumstances. “Covered Entities” may include physicians, pharmacies, health plans and others with whom we do business. With the possible exception of certain employee benefit plans, Purdue is not a “Covered Entity.” However, it is important that all Purdue employees recognize that our customers may be restricted from sharing certain health information with us, particularly if such information might identify any individual patients.

In many circumstances, Covered Entities must obtain permission before they can use or disclose protected health information. Even in situations where permission is unnecessary, companies must still follow certain rules in using or disclosing this confidential data. HIPAA also allows individuals to learn what information has been collected about them by Covered Entities and what will happen to that information.

In the context of adverse event reporting, HIPAA specifically permits disclosure of personally identifiable information that is relevant to the report.

HIPAA’s requirements are extremely complex. Any questions about Purdue’s privacy policies and procedures should be directed to an attorney in the Law Department or a member of the Corporate Compliance Department.

### Penalties

HIPAA violations are criminal and are punishable by substantial monetary fines, as well as possible jail time (for an individual) and probation (for an organization).

(Note: Laws relating to personal health and privacy may be more restrictive in other countries.)

## THE MEDICARE DRUG, IMPROVEMENT, AND MODERNIZATION ACT OF 2003

### Relevant Purpose

The Medicare Drug, Improvement, and Modernization Act of 2003 (MMA) established a Medicare outpatient prescription drug benefit program, among other things.

### Summary of the Law

The MMA created Medicare Part D as an outpatient prescription drug benefit administered by private entities. Part D drug benefits may be made available through entities offering stand-alone prescription drug benefit plans (known as “prescription drug plans” or PDPs), through managed care plans that offer a more comprehensive healthcare benefit (known as “Medicare Advantage Plans” or MA-PDs), and a variety of other arrangements. Discounts and rebates to PDPs and MA-PDs are not included in Medicaid Best Price calculations.

### Penalties

Although most penalties that may be assessed under Part D do not apply to Purdue, the federal money used for Part D drugs brings the program within the purview of the other laws discussed above.

Some activities that may generate scrutiny by the Centers for Medicare and Medicaid Services (CMS) include:

- Failure to generate, report, or document Part D rebate or discount information completely and accurately
- Kickbacks, inducements, and other illegal remuneration
- Inappropriate relationships with formulary committee members, payments to pharmacy benefits managers (PBMs), and formulary placement payments in order to have manufacturer’s products included on a plan’s formulary
- Inappropriate relationships with physicians, including “switching” arrangements, certain services payments, gratuities, and improper entertainment, and
- Illegal off-label promotion

Additionally, it is important to keep as much separation as possible between discussions of Part D rebates and discounts and discussions of commercial rebates and discounts, as it would be inappropriate to “swap” between programs (e.g., offer higher discounts to Part D in order to win a company’s commercial business or vice versa).



## THE PHYSICIAN PAYMENTS SUNSHINE ACT

### Relevant Purpose

The Sunshine Act provisions of the Patient Protection and Affordable Care Act seek to provide increased transparency on interactions between physicians and teaching hospitals and the pharmaceutical, biologics, and medical device industries.

### Summary of the Law

Manufacturers must report payments or other transfers of value to physicians and teaching hospitals annually. Reports must be filed by March 31<sup>st</sup> each year, reflecting all payments and transfers of value to physicians and teaching hospitals for the previous calendar year. The Secretary of Health and Human Services will make reported information publicly available in a searchable format by June 30<sup>th</sup> of each year. It is extremely important that Purdue employees (and certain contractors) responsible for making such payments or transfers of value accurately report such transfers.

The Corporate Compliance Department will service as data stewards, aggregating data and reporting it, but the completeness and accuracy of data are the responsibility of the employees/contractors involved in the payments or transfers of value.

Questions about this law and Purdue's efforts to comply can be directed to [sunshineact@pharma.com](mailto:sunshineact@pharma.com).

### Penalties

Manufacturers that fail to report in a timely and accurate manner may be subject to significant civil monetary penalties.

# POLICIES

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## 1. INTERACTIONS WITH HEALTHCARE PROFESSIONALS AND CUSTOMERS

Under this policy, a “customer” is anyone who may influence purchasing or prescribing of a Purdue product, such as healthcare providers, pharmacists, formulary decision-makers, pharmacy benefits managers (PBMs), or managed care personnel. “Customer” also includes office staff of the above individuals.

### *A. Gifts, Meals, and Entertainment*

It is never appropriate to provide a gift, meal, or entertainment in order to encourage a customer to prescribe, purchase, or order Purdue products.

In addition to our commitment to adherence with all applicable laws, Purdue is also committed to voluntarily complying with the American Medical Association (AMA) guidelines and Pharmaceutical Research & Manufacturers of America (PhRMA) Code relating to gifts and meals provided to healthcare professionals. Links to these documents can be found on the Corporate Compliance Department’s page on Purdue’s intranet.

### **When can a gift be provided to a customer?**

Purdue employees may not give gifts to customers unless they have been approved by a member of the Law Department and the Sr. V.P., Chief Commercial Officer, and are:

- Offered only occasionally
- Not of substantial value (\$100 or less)
- Designed primarily for the education of patients or customers/healthcare professionals (HCPs) and do not have value to the recipient outside of his/her professional responsibilities

Under the revised PhRMA Code, “reminder items” with Company and/or product logos (e.g., pens, pins, note pads) are prohibited.

Gifts may never be provided to customers:

- For the personal benefit of a customer (such as floral arrangements, artwork, music CDs, or tickets to a sporting event);
- As cash or a cash equivalent (such as a loan, gift certificate, savings bond, or lottery ticket); or
- As a price term or in place of a price concession



### When can a meal be provided to a customer?

Under the PhRMA Code, meals may be provided if they are:

- In connection with informational presentations or discussions that provide scientific or educational value
  - Occasional
  - Modest as judged by local standards taking into account the meal provided (e.g., lunch, breakfast), and the economics of the area, and
  - In a venue and manner conducive to informational communication
- In accordance with the PhRMA Code, sales representatives and their immediate managers may only provide meals in an office/hospital setting. Other than in connection with a speaker program, sales representatives and their managers may not provide meals in restaurants. Purdue refers to sales representatives and their immediate managers as Territory Business Managers (TBMs) and District Business Managers (DBMs), respectively.
- For Massachusetts-licensed HCPs, meals provided by any Purdue employee or agent must be provided in the office or hospital setting only
  - For Vermont-licensed HCPs who regularly practice in Vermont, meals, including both in-service and speaker program meals, as well as meals provided by non-commercial personnel, are prohibited

These state laws change frequently. If you have questions regarding specific state laws on meals, contact your manager or Corporate Compliance for guidance.

#### Additionally:

- Meals may be reimbursed to Purdue consultants or provided in connection with Purdue-sponsored consulting or advisory meetings if the consulting services and activities related to the services are the primary focus of the meeting, and any meals are clearly subordinate in terms of time and emphasis
- Financial support for meals or receptions may be provided to third-party sponsors of scientific and educational conferences or professional meetings in accordance with these Healthcare Law Compliance Policies and Purdue's grant policies

### When can entertainment or recreational activities be provided to an HCP?

Under the PhRMA Code, it is not appropriate for Purdue to offer entertainment or recreational activities to an HCP.

Additional guidance on gifts and meals may be available in your department's policies and procedures.

#### **B. Gifts and Meals to Federal Government Employees**

United States federal government employees (full-time and part-time),

#### ADDITIONAL GUIDANCE AND EXAMPLES ON GIFTS TO FEDERAL GOVERNMENT EMPLOYEES

(1) Individuals who work part-time for the federal government (e.g., 4 days a week at a civilian hospital and 1 day at the VA) are still federal government employees, even when they are physically located at a civilian facility. Medical residents are considered federal government employees only when they do rotations at government hospitals.

(2) You may not provide a gift worth more than \$20 to federal government employees even if they reimburse you for the amount over the \$20 limit.

(3) The \$50 annual limit for federal government employees applies to Purdue as a whole. Therefore, if you have spent \$40 on a federal government doctor during the year, another employee taking that doctor to lunch may only spend up to \$10 on that physician.

including but not limited to those who work for the Departments of Defense, Veterans Affairs, and the National Institutes of Health (NIH), are subject to stricter limits on gifts and business courtesies than their civilian counterparts. Certain state employees, including but not limited to employees of certain Medicaid programs, are also subject to stricter limits on what they can receive. The restrictions below are in addition to the restrictions set forth in Section 1.A. of these Policies. If you have questions, you are strongly encouraged to seek guidance from the Law Department or Corporate Compliance.

#### **In general, gifts and meals may be provided to federal government employees only if:**

- The value does not exceed \$20 per person per occasion; and
- Purdue spends no more than \$50 per person per year

#### **Gifts and meals may never be provided to government employees:**

- To encourage the prescription, purchase, order, or recommendation of Purdue products; or
- If the government agency has rules prohibiting such gifts or meals

Any gifts provided to federal government employees in accordance with Section 1.A. of these Policies and valued at more than \$20 should be provided to a department or hospital and not to an individual physician or pharmacist.

#### **With respect to the Veterans Administration, the following policies apply:**

- Employees and contractors may not provide food items of any type or value to Veterans' Affairs (VA) staff (including volunteers and without compensation to employees) or bring food items into VA medical facilities for use by non-VA staff
- Veterans Integrated Service Networks (VISNs) may impose additional restrictive measures on Purdue personnel regarding food and/or refreshments incidental to meetings
- To the extent a VA employee wants to participate in a speaker program or an in-service conducted in a non-VA facility, the \$20/person/event rule and \$50/person/year rule outlined above applies. In all likelihood, this will mean that the VA employee may participate in the education portion of the in-service or speaker program but may not partake in any food or beverage offering
- Educational materials provided at Veterans' Affairs facilities may not bear company logos

Note, too, that some institutions – such as academic or state-owned hospital systems – may have adopted policies and procedures that restrict gifts and meals. You are required to send in such policies for review and approval prior to registering with an institution or customer as set forth in the Company's Standard Operating Procedures.

#### ADDITIONAL GUIDANCE AND EXAMPLES

(1) Certain localities or circumstances may impact spending limits. A good rule of thumb for "modest value" is a meal you would provide to a casual friend. You might buy your friend lunch, but would probably not take your friend to the most expensive restaurant in town.

(2) Many state and all federal government employees are also subject to stricter rules regarding gifts, as detailed in these Policies.

(3) Some institutions and clinics may have more stringent policies. If in doubt or if asked to sign any institutional policy, please contact Corporate Compliance.



#### ADDITIONAL GUIDANCE AND EXAMPLES

(1) Purdue may reimburse healthcare professionals and customers for expenses associated with fee-for-service arrangements, such as reasonable travel and meals. Purdue may not pay for expenses of a guest, spouse, or family members of a consultant.

(2) Wherever possible, fee-for-service arrangements should result in a written work product, such as speeches, papers, or studies. Purdue should review, maintain and, if appropriate, circulate and use copies of these work products.

(3) It is never appropriate to pay healthcare professionals or customers to listen to presentations that might be construed as “sales pitches” or “data dumps.”

(4) Consultants, advisory board members, speakers, and investigators should be selected based on credentials and reputations. Although Purdue may consider whether a healthcare professional or customer has experience with a Purdue product, if such experience is necessary to adequately perform the services, no customer should be used based solely on prescribing volume or potential to generate prescriptions.



(1) Discounts and other concessions that reduce the price of product may not be characterized as “administrative fees,” as this may lead to inappropriate government price reporting.

(2) All questions regarding this policy should be directed to the Law Department.

#### ***C. Speakers, Consultants, Advisory Committees, Clinical Research, and Other Fee-for-Service Arrangements***

Purdue may pay reasonable fees for the performance of bona fide services by healthcare professionals and customers, provided certain criteria are met. These “fee-for-service” arrangements may include, for example, speakers, consultants, participation on advisory committees, and clinical research services.

##### **Fee-for-service arrangements are permitted only if:**

- Purdue needs the services, and that need has been appropriately documented
- Participants are chosen based on their qualifications and expertise
- Participation is limited to the number of people needed to do the work
- Payment is based on the fair market value of the work or services, and
- Purdue and the healthcare provider sign a written contract in a form approved by the Law Department that includes:
  - the legitimate business need for the services
  - a minimum one-year term (with some exceptions)
  - the participant’s qualifications
  - a description of the services, and
  - fair market value compensation

##### **Fee-for-services arrangements may not be made:**

- To encourage healthcare professionals to purchase, prescribe, order or recommend Purdue products
- To encourage off-label use of Purdue products, or
- To reward “high volume prescribers”

#### ***D. Customer Administrative and Service Fees (“administrative fees”)***

From time to time, Purdue may agree to pay administrative fees to certain customers (e.g., wholesalers, group purchasing organizations and pharmacy benefits managers) in connection with certain services and administrative tasks incurred in managing contracts, such as maintaining and updating membership lists or providing data on Purdue products or the marketplace.

All administrative fees must be clearly identified as such in written contracts in a form approved by the Law Department. Administrative fees should not be provided as a discount or as a price concession. If Purdue learns that an administrative fee is being passed through to the end purchaser, an inquiry must be undertaken to appropriately determine how Finance should treat the administrative fee or a portion of it in its government price reporting.

#### ***E. Grants and Charitable Contributions***

In general, all grant requests are to be screened by the Law Department and/or Corporate Compliance. Grants are tangible value given for a specific purpose without the expectation or receipt of substantial tangible value in return. Grants may include the provision of cash or cash equivalents, as well as in-kind items or services. Grants include but are not limited to charitable contributions. All grant requests must be approved by a multidisciplinary Grant Review Committee. Purdue personnel should never imply in any way that the purpose of a grant or other contribution is to motivate increased use of Purdue’s products. Likewise, Purdue personnel must never make any commitment or prepromise a grant to a grant requestor.

##### **Grants may not be provided:**

- to discount the purchase of product or in lieu of a price concession
- to influence or encourage the administration, dispensing, prescribing, purchasing, or recommending of Purdue products by any customer
- to promote off-label use, or
- to reward a “high volume” prescriber
- for Medical Education

##### **Charitable Contributions**

It is Purdue’s policy that employees decline opportunities to make charitable donations when participation is solicited by a customer or potential customer, as such an arrangement could be viewed as a kickback. If a customer, such as a physician or pharmacist or related staff member, asks you to make a donation to his or her favorite charity, you should decline the request. If you believe the request is of merit for consideration by Purdue, then you should consult Corporate Compliance or the Law Department.

Purdue may support certain charitable organizations through appropriate donation of products, services, and funds. All charitable contributions must be approved in advance by the Law Department and also may need approval by a multidisciplinary Grant Review Committee. Additionally, any such donations of pharmaceutical products (including provision of pharmaceutical products at discounted pricing) shall be approved in advance by the Law Department to ensure that such donations are appropriately accounted for, if necessary, in government price reports.

##### **Charitable donations of products or funds may never be made:**

- To encourage anyone to prescribe, order, or recommend Purdue products

#### ADDITIONAL GUIDANCE AND EXAMPLES

(1) Contracts may never be conditioned on Purdue providing a grant. For example, it is inappropriate to provide a grant if a customer refuses to purchase Purdue products unless it receives the grant.

(2) You may not suggest that Purdue will fund a grant if the customer agrees to purchase Purdue products or increase the amount of purchases.



- In exchange for an agreement to prescribe or order Purdue products, or
- In lieu of a discount or price concession or as part of a contract negotiation

#### **F. Data Purchases**

Under some circumstances, Purdue may purchase data from its customers in order to foster increased understanding of scientific or clinical issues, or to provide information in areas that are relevant to Purdue's business activities, such as product utilization. All data purchases must be reviewed in advance by the Law Department. Purdue may never offer to purchase data to induce a customer to purchase, prescribe, or recommend Purdue products or otherwise provide a price concession. Additionally, Purdue may never offer to purchase data that it does not have a bona fide use for or that is redundant to data already in Purdue's possession.

#### **Data purchases may be made only pursuant to written contracts that are separate from product purchase agreements and that specify the:**

- Purpose and nature of the data being purchased
- Fair market value of the data, and
- Duration of the agreement

#### **Data purchases may not be:**

- Used as a price term or in place of a price concession
- Contingent on the purchase of any Purdue products
- Made in return for the performance of marketing tasks, or
- Paid for at an inflated cost

#### ADDITIONAL GUIDANCE AND EXAMPLES

(1) For donations of free products, the recipient must provide Purdue with a written statement that the product is to be or was used for charitable purposes. Donations of \$250 or more must be substantiated by a receipt from the recipient that includes a description of the donation and a good-faith estimate of the value of the donation.



(2) You have been asked by an association with which you interact to purchase a ticket to a table at a fundraising dinner they are holding. What should you do?

If you wish to purchase a ticket (or tickets) to a table, you should follow the instructions in the Grant Review Process SOP found on the Policies & Standards page of the Purdue intranet. These policies require that you first seek approval from your supervisor to request a review by the appropriate committee. If allowed by your supervisor, you must send relevant information to the appropriate committee for approval. Individual tickets must be submitted for approval at least 7 days before the registration deadline and requests for table sponsorship must be submitted at least 30 days before the registration deadline.

## 2. PRICING

### **A. Price Concessions Including Discounts, Rebates, and Free Pharmaceutical Products**

Purdue may, from time to time, provide reduced-price pharmaceutical products via discounts, rebates, free products, or other price concessions to our customers. "Price concessions" are anything that reduces the price of a Purdue product.

It is never appropriate to establish our discount levels or market our products to customers based on the amount of reimbursement that the customers may receive from third-party payors, such as Medicare, Medicaid, private payors or others (e.g., marketing or guaranteeing a "spread").

Any arrangements under which Purdue will offer a price concession to a customer (including but not limited to distributors, group purchasing organizations, physicians, pharmacists, hospitals, managed care organizations, pharmacy benefits managers, or other payors) must be captured in a written contract setting forth the terms of the price concession or rebate in advance. All price concessions must be negotiated at "arms length." This means that the discussion of discounting should not be influenced by any other relationships or transactions between the parties. It is against Purdue policy to provide educational grants or charitable donations as price terms or as price concessions (see Section 1.E. of these Policies pertaining to grants and charitable contributions). Any contract must be in a form that has been approved by the Law Department and Managed Health Strategies. Among other things, written contracts must notify customers that they may have an obligation to report the price concessions to the government.

The actual discounts or rebate levels must be approved in advance by the Commercial Organization in conjunction with the Law Department. Therefore, it is important that Finance approve any proposed arrangements for discounts, rebates, free goods, or other price concessions.

"Bundling" of rebates, discounts, or free products (such as discounting one product type in exchange for the purchase of another product type), or "buy one get one free"– type arrangements are permitted only with the prior approval of the Law Department.

Always remember that Purdue is required to make available to certain government programs (such as Medicaid) the benefit of the "best price"

#### ADDITIONAL GUIDANCE AND EXAMPLES

(1) Purdue should only purchase data when it has a legitimate need for the information it buys. The information purchased must be used by Purdue and should relate to areas relevant to Purdue's business.

(2) Data purchases are not intended to substitute for or subsidize activities that are a part of the customer's normal business expenses.



## SPECIAL CIRCUMSTANCES:

- Purdue may under some circumstances donate free or discounted goods to tax-exempt charitable organizations or to individual patients (e.g., indigent care, such as the Individual Patient Assistance Program (IPAP)), provided the product is not given in order to induce or encourage any entity to prescribe or purchase Purdue products.
- Purdue may, from time to time, contract with government agencies such as the Department of Veterans Affairs, state Medicaid programs, or state pharmaceutical assistance programs. There may be special legal considerations with respect to the discount levels associated with such contracts, and the Law Department should be consulted as soon as possible to advise on negotiating and executing of these contracts.
- Many customers responsible for negotiating rebates and discounts for the Medicare Part D program also negotiate rebates for commercial (non-Medicare) lines of business. It is Purdue policy to separate the negotiation and contracting for Medicare Part D rebates/discounts from commercial rebates/discounts to the extent possible. It is never appropriate to offer anything to the Part D line of business in order to gain goodwill or formulary status with a customer's commercial line of business (or vice versa).

we have offered in the marketplace. Therefore, it is never appropriate to offer “side deals” or other programs to customers in order to circumvent “best price” obligations. It is Purdue policy to report the existence and value of all price concessions to the extent required in all prices that it reports to the government.

### **B. Price Reporting to the Government**

It is Purdue's policy to comply fully with all applicable federal and state laws in reporting prices for pharmaceutical products. For additional guidance regarding price reporting methodologies, please refer to Finance and Managed Health Strategies SOPs.

Variations in or adjustments to the methods of calculation must be approved in advance by the Law Department.

### **C. Product Reimbursement Issues**

It is against Purdue's policy to promote its products based on the “spread.” The spread refers to the customer's profit margin between what it pays a pharmaceutical company for a product and the amount it receives in reimbursement from the government or any other payor. This spread may provide the customer with an additional incentive to purchase that company's products rather than competitor products. The government may consider marketing of reimbursement profit margins to be an improper inducement or kickback.

## 3. INTERACTIONS WITH PATIENTS

### **A. Samples, Coupons, Cards, and Vouchers**

Purdue employees may only distribute samples of, and coupons, cards, or vouchers for, prescription drugs in accordance with the Prescription Drug Marketing Act, the Controlled Substances Act, and other applicable state and federal rules. Samples and vouchers are intended to allow a patient to become familiar with a drug and its properties, and a physician to make informed prescribing decisions. Coupons and cards may also assist patients in paying for their medication if the prescriber deems it appropriate. None of these are intended to reward prescribing practices or benefit prescribers financially.

Purdue monitors outside vendors hired to distribute samples for similar compliance. Any samples, coupons, cards, or voucher programs must be approved in advance by the Law Department.

#### **In general:**

- Samples, coupons, cards, and vouchers may not be sold, given away, or traded
- Samples, coupons, cards, and vouchers for prescription products may only be distributed to licensed healthcare professionals for legitimate uses
- Prescription samples may be distributed only after Purdue approval and receipt of a written request from prescribers. Recipients must fill out a written receipt when prescription samples are delivered
- Purdue employees may never complete a sample request on behalf of a practitioner or falsify any sample request records
- Samples, coupons, cards, and vouchers may not be distributed on the basis of an open-ended or standing request
- The provision of samples, coupons, cards, or vouchers may not be used as a price or contract term
- Samples must be stored under conditions that will maintain their stability and effectiveness and that will protect samples from contamination or other degradation in quality

#### ADDITIONAL GUIDANCE AND EXAMPLES

- (1) Any questions regarding how to respond to government surveys or requests for pricing information should be directed to the Law Department.
- (2) If specifically asked by a customer, you may provide truthful and accurate information regarding the discounts Purdue has offered to that customer or any public and published pricing metrics (e.g., wholesale acquisition cost).
- (3) It is always improper to suggest that a customer will receive a larger “profit” from government reimbursement by purchasing Purdue products rather than a competitor product.



#### ADDITIONAL GUIDANCE AND EXAMPLES

(1) Samples, coupons, cards, and vouchers cannot be given with the intent to reward an individual's prescribing habits or as part of a deal to switch patients from one product to another.

(2) You may not provide samples, coupons, cards, or vouchers to customers to "thank" them for purchasing Purdue products or to provide a discount on the purchase of products. If a sample is intended as a discount, it needs to be treated as such in accordance with Section 2.A. of these policies pertaining to discounts, rebates, and free products.

(3) Recipients of samples, coupons, cards, or vouchers cannot charge patients for samples or submit claims to healthcare programs or insurance for reimbursement for the samples, coupons, cards, or vouchers.

(4) Purdue does not distribute samples of Schedule II controlled substances.

- Employees may not encourage or otherwise provide information to physicians or other customers indicating that they may sell samples, coupons, cards, or vouchers, or seek reimbursement for them
- Employees are required to report the following circumstances immediately to Sales Operations, as they may need to be reported by Purdue to the FDA:
  - significant sample losses, including inventories that cannot be reconciled
  - all thefts of samples
  - record falsification, and
  - diversion of samples
- Co-pay assistance card programs, e.g., Savings Cards, Value Cards, etc. may not be promoted or suggested to be utilized by patients who are enrolled in any state or federal government reimbursement programs, including but not limited to Medicare and Medicaid. This restriction applies to Medicare Part D recipients and includes the period in which a Medicare Part D enrollee is in the coverage gap, often referred to as the "donut hole"

Starting April 1, 2012 and continuing every April 1st thereafter, the Prescription Drug Sample Transparency Act will require each manufacturer to report the identity and quantity of drug samples requested and distributed to healthcare professionals in the previous calendar year.

Similarly, Vermont law requires the reporting of all prescription and OTC samples, including physical samples, coupons, co-pay assistance cards, savings cards, etc., provided to all Vermont-licensed healthcare professionals who regularly practice in Vermont. Purdue will gather and report information regarding the distribution of these items in order to comply with this state reporting requirement. To the extent employees are distributing such samples, as broadly defined by Vermont, quantities and recipients must be tracked.

#### 4. RESEARCH AND CLINICAL STUDIES

All research and clinical studies supported by Purdue must advance legitimate research goals. Thus, support for any research or clinical study cannot be provided with the requirement or expectation that Purdue's support will induce or encourage the prescription, purchase, or order of Purdue products. Any research or clinical study that Purdue sponsors or otherwise funds must be conducted pursuant to a written agreement, approved by the Law Department that, at a minimum, includes:

- A statement of the research or clinical objectives
- An outline of the research or clinical protocol
- A written budget detailing all financial and other support to be provided by Purdue, and
- When appropriate, a requirement for progress reports and a final report in writing

Purdue has policies that provide for publishing information concerning ongoing clinical trials in a clinical trial registry/database that is accessible to the public.

In addition, Purdue has committed to publish in a publicly available database the results of many of its clinical trials. Purdue's policies on clinical trial registry and clinical trial results publications give greater detail on these processes.

Consistent with the requirements of the Federal Physician Payments Sunshine Act and similar state transparency laws, Purdue will report payments and/or transfers of value made to physicians and teaching hospitals in connection with bona fide clinical trial and research activities.



## 5. PRODUCT PROMOTION

Purdue employees and agents may not promote any Company product for uses that are not addressed in the FDA-approved product labeling or Full Prescribing Information (FPI). Please note that this limitation on promotional activities applies to all Purdue employees and agents and is not limited to those in the Commercial Organization. Likewise, employees who are not formally trained on Purdue products should refrain from discussions of product attributes with customers and other external parties.

### In general, Purdue employees or agents may not:

- Use any materials in a promotional context that have not been approved through the Material Review Process
- Make any claims or use any materials that are false or misleading
- Make claims that a Purdue product is safer or more effective than the labeling indicates
- Misrepresent a study or other information pertaining to clinical data, or
- Fail to make clear where the side effects and contraindications information appear, when appearing on multiple pages or located on a different page of a promotional piece

In addition, “fair balance” requires that side effects and contraindication information must be presented with a prominence and readability reasonably comparable to the presentation of effectiveness-related information. Fair balance must exist in our printed materials as well as any oral communications of a promotional nature.

Purdue has additional policies and procedures that specifically address use of promotional, non-branded, and other materials used outside Purdue.

### Examples of some types of promotion:

- Unapproved Products or Indications: Purdue employees or agents may not make any claims of safety or efficacy with respect to products or indications that have not received FDA approval
- Comparative or Superiority Claims: Any claims that compare our product with another product or assert superiority must have received Material Review clearance
- “Disease Awareness”/“Help Seeking” Materials: Purdue produces “disease awareness” or “help seeking” pieces that are not branded and are not intended to promote a particular product. All such pieces are subject to the Material Review Process, as is anything that is not

### ADDITIONAL GUIDANCE AND EXAMPLES

(1) Because clinical studies must promote legitimate and ethical scientific research, studies may not be funded with the intent to “seed” the market with product and encourage product use.

(2) Clinical investigators should be selected based on their scientific credentials and their reputations and not because of volume of prescriptions of Purdue products.

(3) Payments for clinical trials must be fair market value and negotiated at arms-length without regard for any other relationships that may exist between the parties. Disclosure of financial interest must be made in any patient consent forms used in a study.

(4) Recruitment bonuses or “finder’s fees” are not generally appropriate, except that investigators may be paid fair market value for any additional time and effort spent in recruitment where recruitment is particularly difficult (e.g., reimbursement for appropriate advertisements for subjects). Any recruitment bonuses must be approved by the Law Department, set forth in the written agreement with the institution, and approved by the Institutional Review Board (IRB).

an individualized presentation or item. Among other things, a “disease awareness” or “help seeking” piece must not refer to a particular prescription drug product or imply that a prescription drug is the preferred treatment for the condition featured, or discuss unique properties of the drug that allow for its identification

### Journal or reference reprints:

Any journal or reference reprints to be distributed promotionally by Purdue must be approved under the Material Review Process. In no event shall any reprint be disseminated in order to promote the off-label use of a Purdue product.

### Use of promotional materials:

ALL MATERIALS USED IN PROMOTION MUST BE PROVIDED BY THE CORPORATE HEADQUARTERS, AFTER UNDERGOING INTERNAL REVIEW VIA THE COMPANY’S MATERIAL REVIEW PROCESS. A copy of the Material Review Process SOP is available on the Purdue intranet home page. Purdue employees may not change or in any way alter promotional materials once they have been approved for distribution.

### No “homemade” materials may be used for promotional purposes. Some examples of inappropriate “homemade” materials are:

- Altered sales aid pages (e.g., highlighting)
- Thank-you notes with a product message
- Approved reprints with a handwritten note describing study results
- Unapproved journal reprints
- Unapproved newspaper stories

Additionally, no healthcare professionals speaking promotionally on behalf of Purdue may alter a Purdue-approved slide kit, except with written permission from the Law Department. This includes but is not limited to adding, deleting or skipping slides, or re-ordering slides in an approved slide deck. Purdue employees who witness inappropriate behavior (e.g., off-label discussion, misuse of approved materials, etc.), should contact Corporate Compliance at [compliance@pharma.com](mailto:compliance@pharma.com) to address these concerns.

Purdue policy permits only authorized personnel to answer questions and provide information about off-label uses of Purdue products. Such inquiries must be unsolicited.

### ADDITIONAL GUIDANCE AND EXAMPLES

(1) Promotional materials need to be sent by Regulatory Affairs to the FDA prior to or at the time of external dissemination.

(2) Examples of prohibited promotional activities include, but are not limited to:

- Using sales and promotional materials (including, but not limited to: slides, conversion charts, and non-product-specific information) created by an individual employee that have not been formally approved by the Company for field distribution
- Targeting healthcare professionals whose medical specialties suggest they would not ordinarily be prescribing the product for an approved use
- Discussing unapproved or “off-label” use of a Purdue product
- Commercial personnel answering healthcare professionals’ questions on off-label uses. Such questions should be referred to the Medical Services Department (1-888-726-7535)
- Using unapproved messaging in a promotional interaction, even if referencing approved materials

(3) The prohibition on alteration of promotional materials is absolute: among other things, you may not write notes in the margin, highlight certain portions of text, or edit journal reprint articles to emphasize particular sections.

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## 6. PROTECTING CONFIDENTIAL MEDICAL INFORMATION

Purdue is committed to limiting the dissemination of individually identifiable health information including but not limited to compliance with HIPAA (see discussion of this law on Page 10). Purdue will not use or disclose an individual's protected health information, unless it determines that the use or disclosure is allowed without permission, or it obtains the necessary permission. In addition, use and disclosure of protected health information will be limited to the minimum amount of information required to accomplish the purpose of the use or disclosure (i.e., on a "need-to-know" basis).

Purdue has a website privacy policy to safeguard the privacy of Purdue website users and inform users how their information is collected and used by Purdue.

The following are examples of activities that are inappropriate under Purdue policy:

- Disseminating personal health information that identifies a person participating in a clinical trial, outside of those who have a legitimate need to know the information
- Recognizing a person's name who has called or contacted Purdue and sharing information on what products that person is using or their disease state with anyone, or
- Sharing personal medical information of a Purdue employee with others

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(4) If a product is being promoted outside of the United States for use in the United States, all Purdue Healthcare Law Compliance Policies apply, regardless of where the promotional activity occurs.

(5) Because websites are routinely accessible by anyone with Internet access, information on a site hosted in the United States that addresses products sold in the United States should comply with all United States promotional rules and all Purdue Healthcare Law Compliance Policies. Such sites should indicate that the information provided is for U.S. residents only.

## 7. ADVERSE EVENTS (AE), PRODUCT COMPLAINTS (PC), REPORTS OF CONCERN (ROC), and ABUSE AND DIVERSION DETECTION PROGRAM (ADD)

All employees are required to report knowledge of particular information or observation of specified activities, including Adverse Events, Product Complaints, Reports of Concern, and reports pursuant to ADD, as outlined below.

### A. Adverse Event Reporting

Any employee who hears about an Adverse Event (AE) involving a person receiving a Purdue product or an unknown brand of a product with the same active ingredient as a Purdue product must report the AE to the Drug Safety and Pharmacovigilance Group (DSP) within 48 hours of learning the information.

- Marketed Products Adverse Event: An AE is any unintended event associated with the use of the marketed product, whether or not considered related to that particular product. Known side effects (e.g., constipation, nausea) are considered reportable AEs
- Investigational Product Adverse Event: For a product being used in clinical trials (i.e., an investigational product), an AE is any unintended event that occurs while a subject is taking the investigational product or as defined within the study protocol, whether or not the event is related to the use of that product

### B. Product Complaint Reporting

Any employee who hears about a Product Complaint (PC) involving a Purdue product, or an unknown brand of a product with the same active ingredient as a Purdue product, must report the PC to the Corporate Quality Assurance Product Monitoring Group within 48 hours of learning the information. A PC is any complaint concerning any undesirable or unusual occurrence with a product itself or with a product's packaging, labeling, immediate container, closure, or contents. A mere suggestion to change an attribute is not a PC.

### ADDITIONAL GUIDANCE AND EXAMPLES

- (1) Permission for disclosure is generally required for business planning, quality assurance activities, internal compliance, or financial audits, as well as for marketing, clinical trials, and disclosure to the media.
- (2) Permission for disclosure is generally not required for adverse event reporting, product tracking, product recalls, or post-marketing surveillance, as well as certain research uses, and some legal uses.
- (3) Purdue will require other companies that perform services for Purdue and have access to protected health information to protect that information with the same care that Purdue does.



### **C. Reports of Concern**

Certain employees, including Territory Business Managers (TBMs), District Business Managers (DBMs), Regional Business Directors (RBDs), Key Account Managers, Account Executives, Law Enforcement Education and Liaisons, Medical Science Liaisons, Risk Management Field Researchers, and other individuals with field-related responsibilities, are required to submit Reports of Concern (ROC). An ROC is a specific alleged occurrence of diversion of a Purdue Pharma L.P. marketed opioid analgesic.

### **D. Reports Pursuant to ADD Program**

In accordance with Purdue's 10-year settlement agreement with the Attorneys General in 2007, Purdue has established the Abuse and Diversion Detection Program (the ADD Program). Pursuant to the ADD Program, Purdue TBMs, DBMs, RBDs, and certain other field personnel are required to report suspect situations learned of or observed to the Law Department for review and evaluation. Procedures related to this program are outlined in a separate Standard Operating Procedure, incorporated herein by reference, SOP 1.7.1, Abuse and Diversion Detection Program.

Mechanisms for Reporting: AEs, PCs, ROCs, and ADD reports should be made using the following mechanisms:

Item To Report	Reporting Mechanism
Adverse Event (Marketed or Investigational Product)	<ul style="list-style-type: none"> <li>Phoenix Territory Management System reporting functionality, if available</li> <li>E-mail (to "AE Report" or "Drug Safety and Pharmacovigilance" in Outlook)</li> <li>Fax: 203-588-6395</li> <li>Telephone the Purdue Drug Safety Line (1-888-726-7535), prompt #2</li> </ul>
Product Complaint	<ul style="list-style-type: none"> <li>Phoenix Territory Management System reporting functionality, if available</li> <li>E-mail (to "Product Complaints" in Outlook)</li> <li>Fax: 203-588-6395</li> <li>Telephone the Purdue Drug Safety Line (1-888-726-7535), prompt #3</li> </ul>
Report of Concern	<ul style="list-style-type: none"> <li>Phoenix Territory Management System reporting functionality, if available</li> <li>E-mail (to "AE Report" or "Drug Safety and Pharmacovigilance" in Outlook)</li> <li>Fax: 203-588-6395</li> <li>Telephone the Purdue Drug Safety Line (1-888-726-7535), prompt #2</li> </ul>
ADD Report	<ul style="list-style-type: none"> <li>Phoenix Territory Management System reporting functionality, if available</li> <li>Using the ADD Report available on "Policies and Standards" section of the Purdue intranet and faxing it to Drug Safety at 203-588-6395</li> </ul>

#### ADDITIONAL GUIDANCE AND EXAMPLES

(1) If you are unsure whether a remark is an AE or PC, report it to Drug Safety and Pharmacovigilance.

(2) If the AE or PC you hear of concerns an active ingredient in a Purdue product and no manufacturer or brand is evident, report to DSP.

(3) "Unintended" means any event that is not a purpose of the product (e.g., respiratory depression, or nausea).



## 8. PURDUE'S CONFIDENTIAL DISCLOSURE PROGRAM

Purdue encourages employees to report any issues or concerns related to compliance or ethical obligations under laws, regulations, and Purdue policies, including laws governing Federal reimbursement programs, such as Medicare, Medicaid, and FDA regulations. Reports may be made confidentially and anonymously via Purdue's Ethics and Compliance Hotline at 1-877-PURDUE1 or 1-877-787-3831. All reports will be followed up by Corporate Compliance and, where applicable, by additional appropriate individuals.

It is Purdue's policy not to retaliate against any employee for raising issues or reporting concerns in good faith.

In addition to the Purdue Ethics and Compliance Hotline, issues, questions, or reports of known or suspected violations of laws, regulations, ethics, or policies may be made to Corporate Compliance. If you are more comfortable reporting to the head of your department, any officer of the Company, or anyone else in a position of responsibility, you should feel free to do so. What is important is that you make the report.

The Company encourages reports to be made in person, to ensure that we understand your concerns accurately and avoid misunderstandings.

To the extent possible and appropriate under the circumstances, the Company will endeavor to maintain the confidentiality of the identity of anyone who reports a suspected violation of law or policy or who participates in the investigation. However, the need to conduct an adequate investigation and to take corrective action may require disclosure of certain information. In some circumstances, the Company may be required by law to identify a person who makes a report or who is a witness. Employees also should be aware that members of the Corporate Compliance Department and members of the Law Department, as well as others, are legally obligated to act in the best interests of the Company.

## 9. PENALTIES FOR VIOLATING THESE POLICIES

Purdue takes compliance with these policies, and the laws and regulations underlying these policies, very seriously. Employees who fail to comply with these policies, or who negligently or willfully fail to detect and report violations of these policies, will be subject to disciplinary action, including but not limited to:

- additional training
- coaching
- written warning letter
- probation
- suspension
- monetary penalty
- termination of employment

Discipline for such acts or omissions need not be progressive in nature. Purdue may, where appropriate, terminate employment without having imposed any less severe disciplinary measures.

Nothing in these Healthcare Law Compliance Policies is intended to alter an employee's employment-at-will status, to create legal rights, or to create a contract between the Company and any of its employees.





 Compliance Hotline:  
1-877-PURDUE1 (1-877-787-3831)