

Reference Material





Product inventory, account set up and case forms



Account Set Up Form



Account Set Up Completed by: Agent Submit to: RSM

Principal Information

Name	Company Name
Address	
Mobile Phone	Email Address
Non-Compete (Y/N)	If Non-Compete list
	Previous Employer

Authorized Sub Reps

Only those Sub reps listed here by Principal are authorized to sell United products on behalf of designated Agency. Please submit additional forms if more room is needed.

Name	Phone	Email

FedEx Shipper Address Set up

List addresses for FedEx Shipper location set up. Include a shortcut name to identify multiple locations for shipping restock, for example shortcut abbreviation names us as "Home Office" or "Mercy Hsp" or "Fedex HFP Main". Please submit additional forms if more room is needed.

Example

Shortcut Name	Home Office	Address	315 Main St, City, State, Zip
Attention	John Smith	Phone Number	
Email Shipping C	Confirmation To	johnsmith@email.com	n

Shortcut Name		Address	
Attention		Phone Number	
Email Shipping C	Confirmation To		

Shortcut Name	Address	
Attention	Phone Number	
Email Shipping Confirmation To		

Shortcut Name		Address	
Attention		Phone Number	
Email Shipping C	Confirmation To		

Shortcut Name		Address	
Attention		Phone Number	
Email Shipping C	Confirmation To		

UOC USA INC.

15251 Alton Parkway, Suite 100, Irvine, CA 92618 Tel: +1 949 328 3366 Fax: +1 949 328 3368 us.unitedorthopedic.com



Hospital Account Set Up

Facility Name

Type of Business

Contact Info

Phone and Extension

Send invoices via email to:

Send invoices via Fax to:

Invoice via mail?

Name



Hospital Account Set Up Form

Agent should complete this form for hospital accounts for which United products will be sold. This Account set up form is required to set up the billing for all customer accounts prior to the first case being performed and so that Accounting may generate customer invoices and pay commissions. This form may be used for more than one account. Kindly complete all fields to ensure successful account set up.

COMPLETED BY AGENT, SEND FORMS TO: us.accounting@unitedorthopedic.com

Hospitai into	Required for	Billing Set up:

Billing Address				City:		State:	Zip:
Shipping Address				City:		State:	Zip:
Parent Group / GPO							
Type of Business	☐ Profit O	rganization	Sales	Гах Ехе	mption 🗌 Na	tional 🗌	Community
Contact Info	Co	ontract / Pu	rchasing		Billir	g / Accoun	ting
Name							
Phone and Extension							
Send invoices via email to:							
Send invoices via Fax to:							
Invoice via mail?	☐ YES	□ NO					
	Но	spital Info	Required f	or Billi	ing Set up:		
Facility Name							
Billing Address				City:		State:	Zip:
Shipping Address				City:		State:	Zip:
Parent Group / GPO			-				

Contract / Purchasing

□ NO

YES

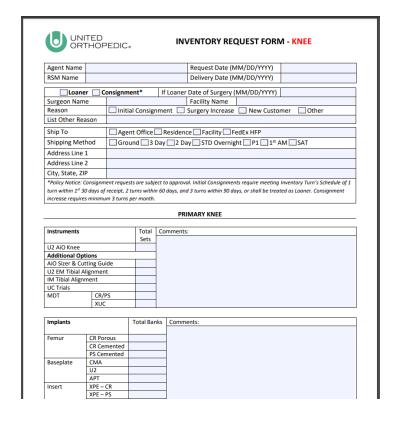
5251 Alton Parkway, Suite 100, Irvine, CA 926	518 T 949.328.3366	F 949.328.3367	FR05-002 rev.04

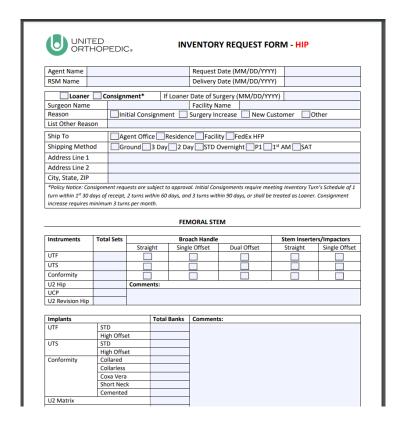
☐ Profit Organization ☐ Sales Tax Exemption ☐ National ☐ Community

Billing / Accounting



Inventory Order Forms







Usage Ticket Form (Bill Only)



Usage Ticket Form

DENNIT TO: us quaternarious size Qualitade the modic com	Today's Date:	
REMIT TO: us.customerservice@unitedorthopedic.com 15251 Alton Pkwy Ste. 100, Irvine, CA 92618	Today's Date:	ay / STD / P1 / 1st am / SAT P1
Phone: 949-328-3366 eFax: 949-328-3368	Restock Location:	dy / 31D / P1 / 1St dill / 3Al P1
Surgery Date:	P.O. #	
Surgeon Name:	Hospital Name:	
MRN. / Case ID No.:	Hospital Address:	
Catalog Number	er/ Lot Number	
Price: \$	Price: \$	
Price: \$	Price: \$	
2: 4	a. A	
Price: \$	Price: \$	
Rep Name:	Sub-total Merchandise:	\$
Rep Signature:	Freight:	\$
OR. Name:	Other:	\$
OR. Signature:	Total Invoice:	\$
New Act bill to address:	Contact Name:	Email:

Company documentation is considered PROPRIETARY and is made available for business operations and review by regulatory agencies. Distribution to third parties without prior permission is prohibited.



Conversion Plan

Example Plan



Agent Conversion Plan (enter Agent Name)

By: (Enter RSM name)

Region: (Enter West or East)

Today's Date: (enter Date)



Corporate Visit Request



Corporate Visit Request Form

Completed by: RSM

Submit to: Jennifer.smith@unitedorthopedic.com

Requestor Nam	ie:		Today's	Date	
Sales Manager					
//	6				
/isiting Agent In Name	tormation		Compan	v Name	
Mobile Phone			Email Ac		
WIODIIE FIIOTIE			Lillali Ac	101 633	
Complete this se	ection if Su	b Reps w	vill be attendi	ng this visitation	on:
Name		Phone		Email	
Requested Visit					
Corporate Dinne	er Require	d?			
If so when:					
Departure Date	:		Departu	re Time:	
Choose Training	5		mary and Revisio		_
Package A or B		B. Pri	mary and Revisio	n Hip / Knee / Onco	ology
Add Objectives	or				
Specific Interest	is .				
Comments					

Company documentation is considered PROPRIETARY and is made available for business operations and review to authorized United Orthopedic Personnel only. Distribution to third parties without prior permission is prohibited.

Corporate Visitation Request Form Rev 02



Compliance policies



Interactions with Health Care Professionals Policy

Interactions with Health Care Professionals Policy UOC USA. Inc.

1.0 Purpose

1.1 This policy is intended to provide all UOC USA, Inc. ("UOC") personnel with guidelines for interacting with health care professionals who are or may be customers of UOC, as well as other individuals in a position to order, refer, or otherwise arrange for the purchase of UOC products (collectively "HCPs") and to supplement UOC's other compliance policies, procedures, and related initiatives relative to sales and marketing activities, and collaborative work with HCPs. This policy applies to all UOC personnel, including without limitation independent sales representatives and their employees and/or sub-representatives.

2.0 Scope

2.1 This policy applies to all UOC personnel, whether such individuals are independent contractors or direct employees of UOC (collectively, "UOC Personnel"). It shall govern all interactions that UOC Personnel have with any HCP who is a past, present, or possible future user of UOC products and any other individual in a position to order, refer, or otherwise arrange for the purchase of UOC products whether such individual is a physician or otherwise.

3.0 Guidelines for Interactions with Health Care Providers

- 3.1 A. UOC Personnel shall not engage in any conduct or provide any inducement to an HCP, other than appropriate product related customer service and support, that is designed or specifically intended to: (a) reward physicians or others for ordering products from UOC, or (b) induce physicians or others to order products from, or generate business for, UOC.
 - B. UOC sales personnel (whether direct employees or independent contractors) may not be involved in the offering, negotiation, or delivery of any personal services contract to any consulting or designing physician who is affiliated with UOC. Furthermore, UOC sales personnel shall not be provided with the specifics of the content of any consulting or designing physician's personal services contract except to the extent that the nature of the services that a consulting surgeon is providing may be made known to any UOC Personnel. In some circumstances, it may be appropriate for UOC's President or his designee to provide input regarding candidates for consulting and/or design services and, furthermore, it may be appropriate in certain circumstances for UOC sales personnel to know what services a consulting and/or designing physician is providing. There are no circumstances under which it is appropriate or acceptable for UOC sales personnel to negotiate or otherwise assist in the execution of a consulting or development agreement.
 - C. UOC Personnel may engage HCPs in business meetings that involve a meal paid for by the UOC Personnel. However, such meals must be modest in value, held in a location conducive to the furtherance of the business discussion, and attended only by individuals with a legitimate business interest in the meeting.

In determining the modest nature of any such meal, geographic factors will be taken into consideration, as will specifics regarding the nature of the business meal and the number of attendees. Any such expenditures are subject to reporting pursuant to UOC's Sunshine Act Policy.

- D. UOC shall not provide reimbursement of any kind for HCPs to attend meetings where Continuing Medical Education ("CME") credit is provided, regardless of whether UOC is the sponsor of any such meeting. Any monies provided to such a meeting in sponsorship of the meeting in general or in sponsorship of a particular speaker should be made directly to the CME sponsoring organization.
- E. UOC Personnel shall abide by all UOC policies and procedures relating to UOC sponsored product meetings and UOC sponsored training and education meetings as same relate to interactions with HCPs, whether such HCPs are UOC customers or otherwise.
- F. UOC Personnel shall comply with all UOC policies and procedures regarding compliance training including without limitation training regarding the health care fraud and abuse laws, internal UOC compliance policies, procedures, and initiatives, and UOC's Corporate Code of Conduct and Core Values.
- G. UOC Personnel shall comply with all regulatory and related requirements as they relate to UOC products, including without limitation in the creation and dissemination, including without limitation in person sales calls, of marketing materials and other publications. All such materials and publications shall be approved by all appropriate UOC regulatory, clinical, and legal personnel.
- H. UOC Personnel shall not provide gifts or other things of value to any HCP, unless the gift has a fair market value of \$100 or less and has patient education or product support value. Branded items of minimal value are not permitted. Gifts with significant patient education value that are in excess of \$100 (e.g., anatomical models, textbooks, patient education materials, etc.) are also permitted but must be approved in writing and in advance by the UOC Compliance Officer. Notwithstanding the foregoing, the giving of gifts is generally discouraged and all UOC Personnel shall seek prior approval from their manager and/or supervisor before providing any gift to an HCP.
- I. UOC Personnel shall only make representations to HCPs regarding UOC products that are true and accurate and all representations regarding the use of UOC products shall be consistent with and limited to those applications for which each UOC product is cleared/approved. UOC Personnel shall not engage in discussions of off-label usage of any UOC product with any HCP.
- J. UOC Personnel shall promptly report any product failure or related issues to UOC's regulatory department or other appropriate personnel and shall endeavor to assist in the investigation, if requested, of any such product issue.
- K. UOC Personnel shall promptly report any violation of this Interactions with Health Care Professionals Policy to the UOC Compliance E-mail at compliance@uocusa.com or in person to the UOC Compliance Officer.
- L. Any violation of this policy or any federal health care program requirement, rule, regulation, or guideline by any UOC Personnel shall result in disciplinary action including without limitation the possibility of termination.

SOP05-005 rev.01

SOP05-005 rev.01



UOC USA INC. Physician Payment Sunshine Act Policy and Procedure

UOC USA INC. Physician Payment Sunshine Act Policy and Procedure

The purpose of this policy is to provide an explanation of and the procedure for the reporting of required expenditures made in connection with a health care professional or a medical teaching hospital pursuant to the Physician Payment Sunshine Act provisions contained in the Patient Protection and Affordable Care Act (the "Act"). The Act requires reporting of certain amounts spent on certain health care professionals by, among other entities, medical device manufacturers who sell their products in the United States. Reporting must be made on an annual basis to the Center for Medicare and Medicaid Services ("CMS") Open Payment Website. The Act is intended to increase transparency of the relationships between physicians and the medical device and pharmaceutical communities and provides significant fines and penalties for a failure to report as required by it. It is UOC's intention to abide by each and every of the applicable requirements contained in the Act and it is the expectation of UOC that all of its employees and independent contractors will behave accordingly.

This Physician Payment Sunshine Act Policy and Procedure (the "Policy") applies to all UOC personnel, employees and independent contractors alike, who come into contact with Health Care Professionals in the course of their work for UOC. Anyone having the potential to interface with Health Care Professionals during the course and scope of their employment or their provision of services for UOC will be bound by the terms and provisions of the Policy. "UOC Personnel" as that term is used herein means any UOC employee or independent contractor subject to the terms and provisions of this Policy.

III. Amounts Required to be Reported:

Reportable spend includes any dollar amounts expended on any Covered Recipient as defined below in connection with the sales and marketing of, or educational initiatives relating to any UOC product, as well as in connection with any design development, or consulting services provided by a Health Care Professional to UOC. This includes without limitation amounts spent on meals (including business dinners and light meals provided in connection with an educational in-service session), travel, educational gifts, consulting fees, royalties, and all other amounts which are spent directly or indirectly on a Covered Recipient. "Covered Recipient" includes the following Health Care Professionals and entities that are potential customers of UOC: 1) Medical Doctors (MDs); 2) Doctors of Osteopathy (DOs); and 3) Medical Teaching Institutions

IV. Procedure for Reporting Applicable Expenditures:

The Procedure for reporting expenditures on customers and potential customers made by UOC Personnel in the sales field is as follows:

Page 1 of 2

- 1 Notices to the Sales Field
- a. On the 5th day of each month each individual who has a reporting obligation will be sent an alert that the prior months sunshine act expense report may now be submitted on or before the 15th business day of the month
- b. On the 10th business day of the month an alert will be sent to all applicable individuals which reminds them that their prior month sunshine act expense

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- reports have not been received and are due on or before the 15th business day of
- c. On the 15th business day of the month an alert will be sent to all applicable individuals which reminds them that their report for the prior month sunshine act expenses are due immediately;
- d. On the 16th business day of the month reports outstanding are considered late and commissions shall be held for a period equal to each business day that the report remains outstanding. See Penalties and Sanctions for Failing to Report; and
- e. E-mails may be sent thereafter indicating which reports are still outstanding, however UOC has no obligation to send such reminders. If sent, these reminders will be a courtesy only and shall not be required in the future.

2. Reporting Procedure

- a. All UOC Personnel required to file monthly reports will be provided an electronic report via DocuSign, which shall be used to provide and submit all required information. The information necessary for a complete reporting is contained in the electronic spreadsheet and any questions regarding such information should be directed to UOC's Executive Administrative Assistant or her designee. Each month's report must be signed and dated by the UOC Personnel submitting same
- b. In the event that any UOC Personnel has no expenditures to report, such individual(s) must provide UOC with a signed certification confirming no spend. The certification language and signature line are found on the Excel Spreadsheet referenced above. A failure to provide a certification as required hereunder is considered the same as failing to report any qualifying expenditure.

3. Penalties and Sanctions for Failing to Report

Any UOC Personnel who has a reporting requirement hereunder but fails to report in a timely fashion will be subject to disciplinary action. In the event that the UOC Personnel failing to properly report is compensated with commissions, monthly commissions in the month in which the failure to properly report happens will be withheld for a period equal to the amount of time the reporting information was late. For purposes of calculating this time period, each calendar day after the 15th business day of the month shall count as one (1) day. Accordingly, a report or certification that is not provided to UOC for a period of five (5) calendar days after the 25th business day of the month shall result in a delay of five (5) calendar days for the payment of commissions to the offending party. In the event that the UOC Personnel who fails to properly report is not compensated with commissions, remedial action will be taken in the discretion of the President or his designee up to and including termination.

V. Amendments and Updates

It is anticipated that UOC along with other medical device manufacturers and other entities to whom the Act applies, will receive continued guidance from the government, including without limitation CMS, which guidance shall impact the content of this Policy. All amendments and modifications to this Policy will be provided in writing to each individual with a reporting obligation and all modifications will be applicable immediately unless otherwise expressly stated in such amendment or modification. A failure to comply with any updated requirement contained in this Policy will subject the non-compliant UOC Personnel to the penalties and sanctions outlined herein.

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Off-Label Discussions

What Does "Off-Label" Mean and What Can You Say to Doctors About Such Applications Presented by UOC USA INC.



What is Off-Label Use?

- Any application of a product that isn't an indicated use as determined by the Food & Drug Administration ("FDA") for each cleared or approved product (included in the Instructions for Use and/or the 510(K) or Approval Documentation
- Sales personnel must ensure that they are well-versed on cleared and/or approved uses of all products that they represent



The Learned Intermediary

- Doctors may utilize off-label applications pursuant to a legal theory that they are "learned intermediaries" or, in English, they are educated about medicine to the degree that they may use a product in a manner not cleared or approved by the FDA if their medical knowledge and experience supports such use.
- Manufacturers and their sales representatives ARENOT CONSIDERED LEARNED INTERMEDIARIES
- Even if a doctor makes it clear that he/she wishes to use an offlabel application without suggestion from a sales representative, the sales representative may not provide information or support regarding such application



What You Should Do If You Receive a Request for Off-Label Information

- If a surgeon requests for assistance with an off-label application during a procedure, you may not provide the doctor with any information except to say that the proposed application is off-label
- If a surgeon requests information about an off-label application in an office or other non-operating room location, you may direct the surgeon to the corporate headquarters



What You May Not Do

- You may not suggest an off-label application for any product
- You may not assist the doctor in the use of a product off-label
- You may not discuss off-label applications even casually if the purpose of your discussion is to encourage the doctor in any way to utilize such an application
- You may not promote, educate about, or otherwise inform any medical professional in the continuum of care regarding an off-label application



UOC USA INC. Health Care Compliance Training for the Newly Engaged Sales Professional

ABRIEF OVERVIEW OF THE FEDERAL LAWS
AND
UOCUSA, INC. BEST PRACTICES

Prepared by: Law Offices of Teresa Ford, PC



What are the Laws? What do they Mean?

- > The Anti-Kickback Statute ("AKS"); Civil and Criminal
 - a criminal **statute** that prohibits the exchange or offer to exchange, of anything of value, in an effort to induce (or reward) the referral of federal health care program business.
- > The Stark Law; Strict Liability
 - Stark Law is a limitation on certain physician referrals. It prohibits physician referrals of designated health services ("DHS") for Medicare and Medicaid patients if the physician (or an immediate family member) has a financial relationship with that entity. A financial relationship includes ownership, investment interest, and compensation arrangements.
 - Strict liability that does not depend on actual negligence or intent to harm
- > HIPAA; Business Associate Agreements
 - **Health Insurance Portability and Accountability Act** an act of Congress, passed in 1996, that affords certain protections to persons covered by health care plans, including continuity of coverage when changing jobs, standards for electronic health care transactions, and privacy safeguards for individually identifiable patient information.
 - HIPAA Business Associate Agreement is a contract between a HIPAA covered entity and a HIPAA business associate (BA) that is used to protect personal health information (PHI) in accordance with HIPAA guidelines.



What are the Laws? What do they Mean?

- > The Civil Monetary Penalties Act ("CMP"); \$\$\$\$\$
 - CMP defined as any **penalty**, fine, or other sanction that: (1) is for a specific amount, or has a maximum amount, as provided by federal **law**; and (2) is assessed or enforced by an agency in an administrative proceeding or by a federal court pursuant to federal **law**.
- ➤ The False Claims Act ("FCA"); Civil and Criminal
 - an American federal law that imposes liability on persons and companies (typically federal contractors) who defraud governmental programs. It is the federal Government's primary litigation tool in combating fraud against the Government.
- Physician Payment Sunshine Act
 - 2010 United States healthcare law to increase transparency of financial relationships between health care providers and pharmaceutical manufacturers.
- > The state laws ...

Federal and/or state health care reimbursement provides the grounds for jurisdiction



AdvaMed's Revised and Restated Code of Ethics

- Effective as of July 1, 2009
- No (non-educational) gifts including branded items no matter how nominal the cost
- New requirements for business dinners
- No entertainment or recreation even if subordinate in time (neither company sponsored nor agent sponsored)
- UOC Follows the Code and Expects All Personnel (whether direct or independent) to Follow the Code



The Sunshine Act

• CMS Open Payment Website:

http://www.cms.gov/Regulations-and-Guidance/Legislation/National-Physician-Payment-Transparency-Program/index.html

- Site for reporting of any and all dollars spent by device manufacturers (among others) on any health care professional; the reporting obligation includes spend by independent contractors working on behalf of a company
- Includes important reference information and Frequently Asked Questions



UOC's Sunshine Act Policy

- Compliance is NON-NEGOTIABLE; all UOC personnel who interact with physician customers must report monthly
- All independent agents as well as direct employees must report *all* amounts spent on physicians for meals, travel, and/or any other expenditure type
- "No spend" requires certification; a report certifying zero spend must be turned in by the regular monthly deadline
- Get spend reports submitted ON TIME and CORRECTLY filled out!



UOC Compliance Guidelines

- > Non-educational items of value (gifts) are prohibited
- > Meals must be incidental to a product presentation and modest in cost
- All Company-sponsored meals, meetings, and trainings must take place in settings conducive to informational exchange; Additionally, no guests are permitted at company sponsored events unless the cost of the guest is covered by the health care professional bringing the guest
- Never provide anything of value conditioned on the use, purchase, or recommendation of Company Products
- > Entertainment of any kind and in any situation is prohibited



Real Life Examples of Do's and Don't's

• DO:

- engage in business discussions about UOC products over a modest dinner in a location conducive to an information discussion
- bring lunch for an in-service or other informational meeting with staff **but** only bring food for those folks who have a need to be there and **do** ensure that you bring a sign-in sheet that requires the printed name and signature of each attendee, submit sign in sheet to UOC
- provide educational and patient informational items to your surgeon customers (textbooks, models, brochures on preparing for surgery, *etc.*)



Real Life Examples of Do's and Don't's

• DO:

- feel free to attend a get together or party at a surgeon's home or a party hosted by him/her elsewhere, **but do not** bring any gifts or other things of value to such an event
- let your surgeons who you take to business dinners know *in advance of the dinner* that spouses and/or guests are not permitted or, at a minimum, that if they come, the surgeon will be responsible for the cost of their dinner
- set expectations with both the surgeons and their office staff as to what is appropriate and what isn't in advance of an issue arising



Real Life Examples of Do's and Don't's

• DON'T:

- invite a surgeon out for drinks if there is no legitimate business objective to the meeting (*i.e.*, introducing a new product, discussing product support concerns, *etc.*)
- **ever** discuss consulting arrangements, design and development opportunities, or clinical study participation with any surgeon customers if you do, you will "poison the well" and UOC will be prohibited from working with any such surgeon in any capacity
- attend sporting or other recreational events with your surgeons you are not permitted to pay for any such events and the appearance of impropriety is too great even if he/she is paying his/her own way
- provide anything of value to a surgeon other than as set out in UOC's compliance policies and procedures including without limitation gifts of any sort (no matter how small or inexpensive), promises regarding paid work with UOC, *etc*.



Compliance Best Practices

- Stop e-mailing ... period ... seriously
- Educate your physician customers about what's OK and what isn't
- Sales personnel should not be involved in any way with consulting agreements or payments
- Ask questions if you have them and make sure that you know UOC's compliance policies and procedures
- Report infractions and other problematic situations so UOC can determine how best to handle



THANK YOU