AQUESTIVE THERAPEUTICS, INC.

COMPLIANCE PROGRAM MANUAL

I. INTRODUCTION

Aquestive Therapeutics, Inc. ("Aquestive") has adopted core values which form the philosophy of how we operate and the culture that defines our company. These values include safety and compliance, innovation, collaboration, high performance and achievement, a focus on our colleagues and commitment to ethical behavior and integrity ("Core Values"). Our mission as a specialty pharmaceutical company is to develop and commercialize innovative, safe, and effective products to solve critical health care problems and meaningfully improve people's lives in accordance with our Core Values and in compliance with all applicable regulations. The U.S. Department of Health and Human Services' Office of Inspector General ("OIG") has issued guidance for pharmaceutical companies which sets forth its views on the fundamental elements of an effective compliance program including: (i) establishing written standards of conduct; (ii) appointing a Chief Compliance Officer to develop and monitor compliance; (iii) establishing education and training programs; (iv) maintaining effective communication with colleagues; (v) ongoing auditing; (vi) screening for providers excluded from participating in federal health care programs; and (vii) investigating noncompliance and fraud. This Compliance Program Manual supports Aquestive's Core Values by outlining the rules and principles applicable to all Aquestive colleagues, agents and vendors ("Aquestive Personnel") for conducting business with integrity and in a manner that is compliant with all applicable state and federal laws and regulations, industry codes, and other guiding principles, including OIG guidance (the "Compliance Program"). Aquestive's Compliance Program is dynamic and, therefore, may be modified over time.

II. SCOPE

All Aquestive Personnel must comply with the Aquestive Compliance Program.

III. STANDARDS OF CONDUCT

A. Policies and Standard Operating Procedures (SOPs)

Aquestive's Compliance Program includes written policies which contain bright line rules, and standard operating procedures ("SOPs") which consist of specific controls and instruction, designed to help Aquestive Personnel carry out their specific job functions. The SOPs referenced in this Compliance Program Manual may only apply to a subset of Aquestive Personnel. However, all Aquestive Personnel are required to have an understanding of the entire Compliance Program and a general understanding of the laws, regulations, and applicable industry standards that apply to Aquestive's business. This Compliance Program Manual does not limit, but rather supplements, all other Aquestive SOPs.

B. The Code of Conduct

As a component of its overall Compliance Program, Aquestive has developed a Code of Business Conduct and Ethics (the "Code of Conduct"). The Code of Conduct establishes our

business standards, practices, and policies applicable to all Aquestive Personnel. The Code of Conduct may be updated from time to time to reflect any changes in such standards, practices and policies and those required by federal or state regulations. All Aquestive Personnel receive a copy of the Code of Conduct and must acknowledge annually that they have read, understand and agree to comply with its requirements.

C. Interactions with Healthcare Professionals, Medical Institutions and Payors

1. The Federal Food, Drug, and Cosmetic Act

The Federal Food, Drug, and Cosmetic Act ("FDCA") is the regulatory framework for prescription drugs, covering research and development, sales and marketing. The FDCA prohibits the introduction of unapproved new drugs and the misbranding of approved drugs in the U.S. marketplace. A drug product is approved for use only as detailed in its label. Any other use is considered "off-label". Off-label promotion is generally prohibited by the FDCA and can cause significant liability to Aquestive. Any proactive statements by any Aquestive Personnel, or materials used to promote its approved products, including all smartphone/tablet applications, blogs, social media, visual aids, brochures, journal advertising, promotional programs, and other sales aids, must be consistent with that product's labeling. All promotions and information provided to healthcare professionals must be fair and balanced and provide information about a product's benefits with information about a product's risk and limitations. These promotional communications must be truthful and non-misleading and otherwise in compliance with FDCA requirements. Aquestive Personnel who interact with healthcare professionals are responsible for learning and understanding the label and/or instructions approved by the Food and Drug Administration of the U.S. Department of Health and Human Services ("FDA") for use of the applicable Aquestive drug(s)/products and, must limit all communications, both verbal and written, to on-label uses consistent with the product labeling. Notwithstanding the foregoing, Medical Affairs may provide to health care professionals scientific information about unapproved products or uses as set forth in this Compliance Program Manual and any applicable Aquestive SOPs.

Aquestive Personnel must comply with the Medical, Legal and Regulatory Review for U.S Drug and Biologic Products SOP which requires all promotional materials to be reviewed and approved through the medical-legal-regulatory review process.

Aquestive Personnel, who interact with payors, formulary committees and related entities, including third-party administrators, responsible for selection, formulary management and reimbursement coverage of new drugs, must comply with the FDA rules, regulations and guidance on communicating healthcare economic information regarding Aquestive approved drug(s)/products, as well as dissemination of information about Aquestive's unapproved products, with payors, formulary committees and other related entities. Communications with payors, formulary committees and others related entities may include information about unapproved use of an approved, cleared or licensed product to assist them in making decisions about coverage. All communications with payors, formulary committees and other related entities must be open, truthful and not misleading and provide appropriate background and contextual information to enable payors, formulary committees and others to make informed decisions.

2. Federal Anti-Kickback Statute

In addition to compliance with the requirements under the FDCA, all Aquestive Personnel must be aware of the Federal Anti-Kickback Statute ("AKS") and the constraints it places on the marketing and promotion of products reimbursable by federal health care programs including, but not limited to, Medicare, Medicaid, Veterans Association, Children's Health Insurance Program and TriCare Health Care Program. In the health care sector, many common business activities, including, for example, sales, marketing, discounting, and purchaser relations, potentially implicate the AKS. Aquestive Personnel must understand that the AKS prohibits practices that may be common or longstanding in other businesses that are not necessarily acceptable or lawful when soliciting federal health care program business. Importantly, Aquestive treats all healthcare professionals as if they are subject to the AKS even if they do not participate in government health care programs.

The AKS is a criminal prohibition against payments (in any form, whether the payments are direct or indirect) made purposefully to induce or reward the referral or generation of federal health care business. The AKS addresses not only the offer or payment of anything of value for patient referrals, but also the offer or payment of anything of value in return for purchasing, leasing, ordering, or arranging for or recommending the purchase, lease, or ordering of any item or service reimbursable in whole or part by a federal health care program. In addition to criminal penalties, violators may be subject to civil monetary sanctions and exclusion from the federal health care programs. Under certain circumstances, a violation of the AKS may give rise to liability under the Federal False Claims Act, or similar state statutes.

The government recognizes that the AKS is so broad that, if read literally, it could restrict many acceptable business arrangements with legitimate purposes. Therefore, the AKS and the corresponding regulations establish a number of "safe harbors" for common business arrangements that are not treated as offenses under the statute. To qualify for safe harbor protection, the business arrangement must be structured and operated precisely to meet all conditions outlined in the safe harbor regulations. Although failure to comply with a safe harbor does not mean an arrangement is illegal, Aquestive will structure arrangements to fit in a safe harbor, whenever possible. It is Aquestive's policy to avoid any arrangements or practices that may present a significant potential for abuse, including certain remunerative relationships with persons or entities in a position to generate, either directly or indirectly, federal health care business for Aquestive such as purchasers, benefit managers, formulary committee members, GPOs, physicians, hospitals, and pharmacists. All arrangements with such persons or entities should avoid the potential to:

1. interfere with, or skew, clinical decision-making;
2. undermine the clinical integrity of a formulary process;
3. increase costs to the federal health care programs, beneficiaries, or enrollees;
4. be a disguised discount to circumvent the Medicaid Rebate Program Best Price calculation;
5. increase the risk of overutilization or inappropriate utilization;
6. be construed as payment for referrals or use of a product; or
7. raise patient safety or quality of care concerns.

Aquestive, like most pharmaceutical manufacturers and their agents, may have a variety of remunerative relationships with persons or entities in a position to refer, order, or prescribe or influence the referral, ordering, or prescribing of its products. These remunerative relationships potentially implicate the AKS. The federal government has identified the following risk areas for pharmaceutical manufacturers:

1. switching arrangements whereby a pharmaceutical manufacturer offers prescribers cash payments or other benefits each time a patient's prescription is changed to the manufacturer's product from a competing product;
2. gifts or gratuities paid to prescribers;
3. entertainment or travel for providers; and
4. payment to referral sources for consulting or advising.

Any practice or arrangement that creates the potential for abuse or does not fit into an AKS safe harbor must be referred to the Chief Compliance Officer for review and approval, in consultation with legal counsel ("Legal"), as necessary.

3. The False Claims Act

The False Claims Act ("FCA") is a federal law that imposes liability on any person who submits or induces someone else to submit a false claim for products reimbursable by federal health care programs including, but not limited to, Medicare, Medicaid, Veterans Association, Children's Health Insurance Program and TriCare Health Care Program. The government has the ability to bootstrap a violation of the AKS into a violation of the FCA on grounds that a violation of the AKS constitutes a false or fraudulent claim that is a sufficient basis for FCA liability. Therefore, Aquestive also faces FCA liability when arrangements are not properly structured to comply with the AKS.

4. PhRMA Code

The Pharmaceutical Research and Manufacturers of America (PhRMA) Code on Interactions with Healthcare Professionals, adopted in 2002, and as amended in 2010, found at http://www.phrma.org) ("PhRMA Code") sets forth important recommended standards for relationships and interactions with health care professionals. Aquestive has adopted the PhRMA Code in its entirety as part of this Compliance Program. As such, Aquestive Personnel involved in sales and marketing are required to understand and comply with the PhRMA Code.

D. Regulatory and Medical Affairs Teams

The Aquestive Regulatory and Medical Affairs Teams, in consultation with Legal, have an important role in ensuring Aquestive avoids certain exposures related to fraud, waste and abuse.

1. Drug Development and Approval

The FDA promotes and protects the public health through its regulation of clinical research. New drugs may not be introduced into the U.S marketplace unless they have been approved by the FDA through the new drug approval process, which requires the applicant to demonstrate that the new drug is safe and effective for its intended use. Before initiating a clinical trial in order to

gather the evidence necessary to obtain approval for a new drug, a sponsor must file with the FDA an Investigational New Drug (IND) application showing that the new drug is reasonably safe to conduct the clinical trial in the United States.

Good Clinical Practices ("GCPs") are the standards for the design, conduct, performance, monitoring, auditing, recording, analysis and reporting of clinical trials in a manner which ensures the integrity of the data and the safety of human subjects. The IND, patient informed consent, Institutional Review Board regulations and related guidelines, and the International Conference on Harmonization (ICH) guidelines set the standard for the conduct of clinical trials in accordance with GCPs.

Aquestive's Medical Affairs Team, in consultation with Aquestive's Regulatory Team, is responsible for Aquestive's drug development activities, including trial initiation and oversight. Such activities include, but are not limited to, selecting investigators for the conduct of clinical studies, monitoring clinical studies to ensure compliance with the protocol and federal regulations, reporting adverse effects or risks associated with the study or the investigational product, and ensuring data integrity. If a clinical study confirms that a new drug is safe and effective, the Regulatory team will oversee FDA filings seeking approval for the product, including submitting required FDA filings. The FDA has various authorities to ensure the continued monitoring of the safety and effectiveness of drug products, and to assure that the benefit-risk balance determined in the NDA approval is maintained. Manufacturers may be asked to submit post-market safety reports to address adverse experiences or to engage in post-approval studies for approved products. Regulatory will oversee ongoing monitoring and submission of data to the FDA.

2. Sponsored Trials

Aquestive supports both investigator-initiated studies and company sponsored trials. The selection of providers to serve as investigators for clinical research studies may raise issues under the AKS. To maintain the objective clinical focus and to avoid exposure under the AKS, all clinical research activities, including requests from providers or other third parties for funding from Aquestive for clinical research, must be reviewed and approved in accordance with Aquestive's SOPs. Such review will be independent of the sales and marketing activities and will not take into consideration any metrics related to sales or referrals. Payments made to clinical investigators may create a conflict of interest and should be structured to eliminate the potential for improper incentives, should be transparent and reflect fair market value for bona fide services to minimize kickback risks. Aquestive will be required to disclose to the FDA certain information about compensation to, and financial interests of, clinical investigators in studies used to support product efficacy or safety. Additional disclosure obligations for payments to physicians may attach under other federal and state disclosure laws.

3. Publications

Aquestive's participation in any presentation or publication of any research results will be in accordance with Aquestive's SOPs on research presentations and publications.

4. Grants

Grants and charitable contributions are "non-return on investment" endeavors. That means that it is never appropriate to expect any direct return to Aquestive from the funding of a grant or charitable contribution. Funding that is conditioned, in whole or in part, on the purchase of product implicates the AKS, even if the educational or research purpose supported by the grant is legitimate. Aquestive Personnel cannot have any influence over the substance of an educational program or presenter that is supported by a grant, otherwise there is a risk that the educational program may be used for inappropriate marketing purposes.

The Accrediting Council for Continuing Medical Education ("ACCME") identifies, develops, and promotes standards for quality of continuing medical education ("CME") programs used by physicians to maintain competence and incorporate new knowledge to improve medical care for patients. Aquestive may support CME programs conducted by an independent third-party authorized to provide CME (i.e., an ACCME accredited provider), such as a hospital, medical society, or educational vendor. Such "commercial support" for CME programs must comply with ACCME's Standards for Commercial Support and Aquestive's SOPs.

The Chief Medical Officer, with input from Medical Affairs, will review and approve requests for grants and CME support.

5. Support Services

To the extent Aquestive offers purchasers any support services in connection with the sale of its products, such as billing assistance tailored to the purchased products, reimbursement consultation, or other programs specifically tied to support of the purchased product, such patient support services will be overseen by Commercial, in consultation with Legal, as necessary, and must be structured to comply with the AKS.

6. Field-Based Medical Affairs

Aquestive Field Based Medical Affairs ("FMA") colleagues are dedicated to providing stakeholders with scientific and clinical information through research and publications and establishing a rapport with key members of the medical and scientific communities. While it is against Aquestive policy and illegal to promote off-label uses of a product, FDA laws and regulations are not intended to limit "scientific exchange" about drug products. Medical Affairs may provide scientific information about unapproved products or uses in the context of an exchange of scientific information. All interactions between providers and FMA, including responses to unsolicited requests for off-label information, will be in accordance with Aquestive's SOPs, and all materials intended for standard FMA use including, but not limited to, slides and educational material will be prospectively reviewed and must be approved for external use by Medical Affairs.

E. <u>Relationships with Patient Organizations</u>

Patient Assistance Programs that offer cash subsidies or free or reduced price drugs have become the focus of investigation by the OIG. Aquestive is committed to ensuring access to

Aquestive products to beneficiaries that need financial aid but maintains SOPs to ensure that such assistance does not run afoul of the AKS or other federal and state laws. Relationships with Patient Assistance Programs will be reviewed by the Aquestive Marketing Team and the Chief Compliance Officer, in consultation with Legal, as necessary.

F. Samples

The Prescription Drug and Marketing Act ("PDMA"), which is part of the FDCA, prohibits the sale, purchase, or trade, or offer to sell, purchase or trade, a prescription drug sample, voucher and/or coupon. PDMA prevents samples from being introduced into the market for sale.

A drug sample is defined under law to be a unit of the drug that is not intended to be sold and is intended to promote the sale of the drug. Failure to comply with the requirements of PDMA can result in sanctions. In some circumstances, if the samples have monetary value to the recipient (e.g., a physician) and are used to treat federal health care program beneficiaries, the improper use of samples may also trigger liability under other statutes, including the False Claims Act and the AKS.

Therefore, Aquestive will closely follow the PDMA requirements (including all documentation requirements) in regard to providing samples. In addition, Aquestive will: (i) train its sales force to inform sample recipients in a meaningful manner that samples may not be sold or billed; (ii) clearly and conspicuously label individual samples as units that may not be sold (thus minimizing the ability of recipients to advertently or inadvertently commingle samples with purchased product); and (iii) include on packaging and any documentation related to the samples (such as shipping notices or invoices) a clear and conspicuous notice that the samples are subject to PDMA and may not be sold.

G. Transparency Laws

Aquestive will comply with the requirements of the Sunshine Act created by the federal Affordable Care Act. The Centers for Medicare and Medicaid Services ("CMS") fulfills the Sunshine Act's mandate via the Open Payments Program that collects information about payments and other transfers of value made by pharmaceutical drug companies (like Aquestive) to prescribers and teaching hospitals. The data submitted to the Open Payment Program is publicly available.

The payments and transfers of value covered by the Sunshine Act include arrangements with covered recipients that are licensed physicians, physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists and certified nurse-midwives ("prescribers") that:

- Make payment directly to prescribers or teaching hospitals (known as direct payments).
- Make payment indirectly to prescribers or teaching hospitals (known as indirect payments) through an intermediary such as a medical specialty society.
- Make payments to another party (known as third party payments) designated by prescribers or teaching hospitals such as a hospital's non-profit foundation.

Examples of covered activities include, but are not limited to, clinical research, consulting or advisory relationships, meals, transportation, lodging, prescribers education (including continuing medical education at accredited or certified events), sharing best practices, donations of drugs or equipment, and any investment or ownership in Aquestive, including stock or stock options. The Sunshine Act contains narrow exceptions such as educational materials or items directly benefiting patients and 90-day supply of single-use or disposable evaluation products.

A majority of states have adopted laws comparable to the Sunshine Act (being referred to collectively with the Sunshine Act as "Transparency Laws").

Aquestive has a comprehensive program in place to help collect, track and report the payments and transfers of value by the company covered by the Transparency Laws and will report such payments as required to CMS and applicable state regulatory authorities. All such payments or transfers of value must be based on fair market value of the service or product and will be set forth in a written agreement. Aquestive's Compliance Program includes SOPs, training, and tools to help Aquestive Personnel consistently conduct these activities responsibly and in compliance with legal and regulatory standards and allows Aquestive to truthfully certify compliance in accordance with the Transparency Laws. Due to the complex and comprehensive nature of the reporting requirements under the Transparency Laws, any payments or transfers of value to be made to a prescriber or teaching hospital that are outside of the authorized Aquestive policy must be pre-approved by the Chief Compliance Officer, in consultation with Legal, as necessary.

Any questions about the requirements of the Transparency Laws or reporting payments or transfers of value should be referred to the Chief Compliance Officer.

H. Government Pricing and Data Integrity Requirements

1. Government Reimbursement Requirements

Aquestive participates with various federal and state drug purchase programs. Under the Medicaid Drug Rebate Statute, Aquestive must give Medicaid the lowest price that it offers to any purchaser, except some federal customers that may receive a lower price. Aquestive may enter into an agreement with the federal government to provide rebates to state Medicaid programs, in exchange for Medicaid coverage of Aquestive's products.

Aquestive will comply with all federal and state laws and regulations governing Aquestive's participation in government programs for the purchase, payment or reimbursement of its products. Aquestive will comply with all federal and state laws and regulations that require calculation and reporting of various pricing data for Aquestive products. At the federal level, these include Average Manufacturer Price, Best Price, Average Sales Price, Non-Federal Average Manufacturer Price, Federal Ceiling Price and 340B Ceiling Price. At the state level, certain states have statutory price reporting requirements, including Vermont, Texas, and New Mexico.

Aquestive will maintain the necessary systems through vendors, personnel, policies and procedures in place to achieve and maintain compliance with all authoritative guidance including, without limitation, applicable regulations, laws and guidance related to these government drug purchase programs.

2. Discounts

Discount arrangements are prevalent in the pharmaceutical industry and are highly scrutinized by both federal and state government authorities, particularly because of their potential to implicate the Best Price requirements of the Medicaid Rebate Program or create a possible violation of the AKS. The Medicaid Rebate Program in many instances requires that states receive rebates based on the Best Price offered by a pharmaceutical manufacturer to other purchasers, including to insurance companies, GPOs and PBMs; therefore, the government is concerned that manufacturers could have a financial incentive to hide de facto pricing concessions to other purchasers to avoid passing on the same discount to the states. Because of the potential direct and substantial effect of such practices on federal and state health care program expenditures, any remuneration provided by Aquestive to a purchaser, however characterized, must be carefully scrutinized and comply with regulatory requirements and Aquestive's Pricing Policy.

Public policy favors open and legitimate price competition in health care. Thus, the AKS contains specific safe harbors for discounts (and similar payment arrangements such as rebates) offered to customers that submit claims to the federal health care programs; provided that the discounts are properly disclosed and accurately reported. However, to qualify for the exception, the discount must be in the form of a reduction in the price of the good or service based on an arms-length transaction. In other words, the exception covers only reductions in the product's price. Moreover, the regulations provide that the discount must be given at the time of sale or, in certain cases, set at the time of sale, even if finally determined subsequent to the time of sale (i.e., a rebate). In addition, under the AKS, offering remuneration to a purchaser or referral source is improper if one purpose is to induce the purchase or referral of program business. Any arrangement that does not comply with these requirements or Aquestive's Pricing Policy must be reviewed and approved by the Pricing Committee and the Chief Compliance Officer, in consultation with Legal, as necessary. Any lump sum payments for inclusion in a formulary or for exclusive or restricted formulary status may be problematic and should also be approved by the Chief Compliance Officer, in consultation with Legal, as necessary.

3. Data Integrity Requirements

Generally, AWP or pricing information is reported by pharmaceutical drug manufacturers. It is essential that all of the information reported by Aquestive to the government regarding product pricing is accurate and discloses all required information. Many federal and state health care programs establish or ultimately determine reimbursement rates for pharmaceutical manufacturers, either prospectively or retrospectively, by using price and sales data directly or indirectly furnished by pharmaceutical manufacturers. The government sets reimbursement with the expectation that the data provided are complete and accurate. The knowing submission of false, fraudulent, or misleading information is actionable. A pharmaceutical drug manufacturer, like Aquestive, may be liable under the FCA if government reimbursement (including, but not limited to, reimbursement by Medicare and Medicaid) for the manufacturer's product depends on information generated or reported by the manufacturer and the manufacturer has knowingly failed to generate or report such information completely and accurately. Manufacturers may also be liable for civil money penalties under various laws, rules and regulations.

Given the importance of the Medicaid Rebate Program, as well as other programs that rely on Medicaid Rebate Program benchmarks (such as the federal 340B Drug Discount Program), manufacturers, like Aquestive, need to pay particular attention to ensuring that the calculation of AWP and Best Price is performed accurately and that the appropriate rebate amounts are being paid.

Therefore, Aquestive will base its AWP reporting practices and methodology on commercially reasonable standards and fully independent of any marketing considerations and in compliance with Aquestive's Pricing Policy. Aquestive's reported prices will accurately take into account price reductions, cash discounts, free goods contingent on a purchase agreement, rebates, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits offered to some or all purchasers. Any discount, price concession, or similar benefit offered on purchases of multiple products should be fairly apportioned among the products. Underlying assumptions used in connection with reported prices must be reasoned, consistent, in compliance with Aquestive's Pricing Policy, and appropriately documented. Aquestive will retain all relevant records reflecting reported prices and efforts to comply with federal and state health care program requirements.

I. Clinical Operations

1. Manufacturing/Quality

Aquestive will maintain SOPs and risk management approaches to meet the requirements of the FDA's standards for manufacturing and testing as set forth in the FDA's current good manufacturing practice (cGMP) regulations. All Aquestive Personnel performing activities relating to the manufacture and/or testing of Aquestive products will be qualified to perform such tasks and will be required to complete training on cGMP requirements and Aquestive's SOPs relating to manufacturing and quality. Such SOPs will be maintained in Master Control and will be readily accessible to such Aquestive Personnel.

2. Environmental/OSHA

The Occupational Safety and Health Administration ("OSHA") sets and enforces standards for ensuring a safe and healthful workplace. Aquestive must comply with OSHA requirements which are set through statutes, standards, regulations, and interpretation letters. Aquestive will maintain SOPs for ensuring compliance with OSHA standards.

3. Recalls

A recall is a method of removing or correcting products that are in violation of laws administered by the FDA or are otherwise defective. The degree of hazard and the extent of distribution of a defective product will dictate the overall recall strategy. Aquestive maintains SOPs to establish a program for prompt reaction and effective dissemination of information in the event a recall of an Aquestive product is required. Regulatory will make recommendations to management regarding the need for a recall of an Aquestive product and will oversee development and implementation of the approved recall strategy.

J. Human Resources

1. Colleague Handbook

Aquestive's Human Resources Team ("Human Resources") will maintain a Colleague Handbook which contains information about Aquestive's employment policies, company rules, and other key information for staff.

2. Non-Employment or Retention of Sanctioned Individuals

In compliance with applicable state and Federal law, Aquestive will not employ any individuals who have been convicted of a criminal offense related to health care or who are listed by a federal agency as debarred, excluded or otherwise ineligible for participation in federally funded health care programs. Human Resources will check federal databases before hiring an individual and on a periodic basis to ensure continuing eligibility of colleagues in accordance with Aquestive's SOPs. In addition, all agents and vendors providing services to or on behalf of Aquestive must meet these same requirements.

In the event, any Aquestive Personnel is accused of a criminal charge or proposed debarment or exclusion, such individuals will be removed from direct responsibility for or involvement in any federally funded health care program. If resolution results in conviction, debarment or exclusion of the individual, Aquestive will terminate its employment of that individual and any non-employed Aquestive Personnel will be prohibited from providing any further service to or on behalf of Aquestive.

K. Data Security/Privacy

Aquestive is responsible for ensuring various types of data collected and processed by Aquestive is handled carefully and in compliance with applicable state and federal privacy laws and regulations. Aquestive develops and maintains SOPs to facilitate compliance with applicable privacy laws and regulations relating to information privacy, communication privacy, data security, unfair/deceptive trade practice and consumer protection laws. In addition, all agreements related to the acquisition, use or release of individually identifiable information must be reviewed by Legal.

L. Other Legal Requirements

1. Antitrust

Aquestive is committed to compliance with federal antitrust laws that prohibit business practices that unreasonably deprive consumers of the benefits of competition, resulting in higher prices for inferior products and services. Federal law recognizes that certain arrangements between firms, such as competitors cooperating to perform joint research and development projects, may benefit consumers. The law does not condemn all agreements between companies, only those that threaten to raise prices to consumers or to deprive them of new and better products, such as agreements among competitors to fix prices, rig bids, and allocate customers. Federal law

also prohibits the monopoly of any part of interstate commerce and certain forms of price discrimination in the sale of commodities, including pharmaceuticals to resellers or distributors.

The majority of states have also adopted antitrust laws which are modeled after their federal counterparts and in many cases extend beyond federal antitrust law to broadly cover "unfair" and "deceptive" trade practices.

Aquestive will not engage in any anti-competitive discussions with competitors and will not enter in agreements with competitors regarding prices, strategic plans, suppliers or customers. Any questions regarding federal or state antitrust laws should be referred to Legal.

2. Bribery

Aquestive prohibits Aquestive Personnel from offering, giving, receiving, or soliciting anything of value for the purpose of influencing the action of an official in discharge of his/her public or legal duties. Both federal law and international law make it a crime to offer or promise anything of value to any public official with an intent to influence that person's official act. Such laws provide that violators will be fined for the offense of bribery. Aquestive Personnel are also prohibited from requesting, seeking, or accepting bribes.

Aquestive requires that any payments made or benefits provided to foreign officials must be subject to review in accordance with Aquestive policies. Any questions about compliance with bribery laws or interactions with public officials should be referred to the Chief Compliance Officer, in consultation with Legal, as necessary.

3. Sarbanes Oxley Act

The Sarbanes-Oxley Act ("SOX") is a federal law that applies to publicly held U.S. corporations and establishes extensive civil and criminal penalties for non-compliance. SOX requires companies to maintain verifiable security controls to protect against disclosure of confidential data and to track personnel to detect data tampering that may be fraud related. To avoid liability under SOX, Aquestive is required to safeguard its data responsibly to ensure that its financial reports are not based upon faulty data, tampered data, or data that may be highly inaccurate. These safeguards must be externally verifiable by independent auditors so that independent auditors may disclose to shareholders and to the public possible security breaches that affect company finances. Security breaches must be reported. Aquestive is committed to operating in compliance with SOX. Any questions about compliance with SOX should be referred to the Chief Compliance Officer, in consultation with Legal, as necessary.

4. Lobbying/Government Relations

Lobbying activities are subject to significant regulatory oversight from both federal and state government authorities. Federal law defines lobbying activities to include:

- any effort to influence the formation, modification, adoption, or administration of any federal legislation, regulation, order, rule or position of the federal government;
- any attempt to influence the nomination or confirmation of any individual to federal office; and

- any endeavor to influence the negotiation, award or administration of a federal contract or grant.

Aquestive is committed to conducting all lobbying activities in compliance with federal, state and local laws. Only Aquestive Personnel authorized by the Chief Executive Officer ("CEO") may engage in lobbying activities on behalf of Aquestive or retain a third-party lobbyist on Aquestive's behalf. Any Aquestive Personnel who is uncertain whether his or her activities might constitute lobbying should contact the Chief Compliance Officer, who shall consult with Legal, as necessary.

5. Campaign Contributions

Federal and state laws generally prohibit a corporation from making contributions to candidate and political parties. In addition, as discussed above, anti-bribery laws impose criminal penalties for offering gifts to government officials in exchange for a change in policy, entering into a contract, or agreeing to engage in any official act. Aquestive Personnel may not make contributions to political candidates or causes on behalf of Aquestive. Any proposed donation or expenditure of corporate funds that relates to a political event, election, or that is requested by a political party, candidate or elected representative must be submitted for prior review and approval by the Chief Compliance Officer, in consultation with Legal, as necessary.

Aquestive Personnel have the right to participate in the political process by making personal contributions from personal funds, subject to applicable legal limits. Aquestive Personnel will not be reimbursed by Aquestive directly or otherwise through compensation for personal contributions. Aquestive Personnel may voluntarily participate in campaign activities, but must do so on their own time, or by taking paid time off.

6. Retention of Records

Aquestive will ensure that all records required either by federal or state laws or by the Compliance Program are created and maintained for a minimum of seven (7) years, or such longer period as required by law, and that the government will have access to records, as required.

IV. CHIEF COMPLIANCE OFFICER

The designated Chief Compliance Officer for Aquestive is Lori Braender who can be contacted onsite at Aquestive or at 908-941-7037 or through the confidential toll-free helpline at 866-777-9049 or the dedicated email address at AQST@openboard.info. The Chief Compliance Officer is responsible for developing compliance policies and standards, overseeing and monitoring Aquestive's compliance activities, and achieving and maintaining regulatory compliance. The Chief Compliance Officer has been authorized by senior management to undertake and comply with these responsibilities and has open access to senior management, including the CEO and/or Board of Directors. From time to time, Aquestive may designate a replacement Chief Compliance Officer, as necessary.

The role of the Chief Compliance Officer includes:

- overseeing and monitoring implementation of the Compliance Program;
- reporting on a regular basis to Aquestive's Board of Directors, the Nominating and Governance Committee of the Board of Directors, the CEO, president, general counsel (if different from the Chief Compliance Officer) and the Compliance Committee on compliance matters and assisting these individuals or groups to establish methods to reduce Aquestive's vulnerability to fraud and abuse;
- periodically revising the Compliance Program, as appropriate, to respond to changes in Aquestive's needs and applicable requirements of federal and state health care programs, identified weakness in the Compliance Program, or identified systemic patterns of noncompliance;
- developing, coordinating, and participating in a multifaceted educational and training program that focuses on the elements of the Compliance Program, and seeking to ensure that all affected Aquestive Personnel and management understand and comply with pertinent federal and state standards;
- ensuring that independent contractors and agents, particularly those agents and contractors who are involved in sales and marketing activities, are aware of the requirements of Aquestive's Compliance Program and applicable Aquestive SOPs with respect to sales and marketing activities, among other things;
- coordinating personnel issues with Human Resources to ensure that the List of Excluded Individuals/Entities has been checked with respect to all Aquestive Personnel;
- assisting Aquestive's internal auditors in coordinating internal compliance review and monitoring activities;
- reviewing and, where appropriate, acting in response to reports of noncompliance received through the hotline (or other established reporting mechanism) or otherwise brought to his or her attention (e.g., as a result of an internal audit or by legal counsel who may have been notified of a potential instance of noncompliance);
- independently investigating and acting on matters related to compliance, including the responsibility of directing and coordinating internal investigations (e.g., responding to reports of problems or suspected violations) and recommending appropriate resulting corrective action, as necessary (e.g., making necessary improvements to policies and practices, and taking appropriate disciplinary action), with various Aquestive teams and functions;
- ensuring appropriate reporting of any self-discovered violations of federal health care program requirements, in consultation with Legal if different from the Chief Compliance Officer; and
- serving as a member of Aquestive's Compliance Committee.

The Chief Compliance Officer has the authority to review all documents and other information relevant to compliance activities, including contracts with the government or potential referral sources, to determine whether Aquestive is in compliance with state and federal health care program reporting and rebate requirements and to examine interactions with health care professionals that could violate kickback prohibitions or other state or federal health care programs requirements. Where appropriate, the Chief Compliance Officer should seek the advice of Legal (if different than the Chief Compliance Officer) about these matters

In addition to the Chief Compliance Officer, Aquestive has a Compliance Committee currently composed of the Senior Vice President, General Counsel, Chief Compliance Officer, Chief Financial Officer, Senior Vice President, Human Resources, Senior Vice President, Business Process and Information Technology, and Director of Compliance. Colleagues can report any suspected or actual violations to any member of the Compliance Committee. This Compliance Committee will be comprised of individuals from various functions and provide subject matter expertise and assistance to the Chief Compliance Officer. The CEO may change or appoint new members to the Compliance Committee from time to time.

Aquestive, through its Chief Compliance Officer, will monitor the HHS OIG fraud alerts and identify any new alerts that apply to Aquestive and oversee the education of all applicable Aquestive Personnel. If any new alert identifies any conduct that needs to be addressed or requires any changes in Aquestive's policies or SOPs, Aquestive will take all reasonable steps to address the new requirements, including (if necessary) initiating an investigation and correction of any identified problems to ensure compliance.

V. EDUCATION AND TRAINING

All Aquestive Personnel will be required to obtain appropriate compliance and ethics training, especially individuals involved in sales, marketing and medical affairs. Such training emphasizes Aquestive's commitment to compliance with all laws, regulations and guidelines of federal and state programs. This compliance training includes training on topics such as the AKS and other issues relating to fraud, waste and abuse. Training of sales and marketing personnel highlights the prohibition against offering remuneration in return for referrals. Training will be conducted at least annually and repeated at regularly scheduled times, using a variety of teaching methods to ensure that all colleagues fully comprehend the implications of failing to comply with Aquestive's compliance plan and all applicable health care program requirements. The training and education program covers Aquestive's SOPs and Code of Conduct and reinforces that strict compliance with all applicable laws and Aquestive's policies is a condition of employment. Failure to comply with any required training may result in disciplinary action, including termination.

VI. COMMUNICATION

A. Access to the Chief Compliance Officer

Aquestive believes that open line of communication between the Chief Compliance Officer and Aquestive Personnel is critical to the successful implementation and operation of the Compliance Program. In accordance with the Aquestive Code of Conduct and the Compliance Program, reporting of suspected or actual violations is required and can be done anonymously. Any colleague should ask, and avoiding guessing, if there is confusion or a question on what is appropriate under the Compliance Program or the Code of Conduct. Aquestive will enforce a non-retribution policy.

B. Anonymous Reporting Options

To encourage anonymous reporting of suspected misconduct, Aquestive will establish a hotline, and may in the future adopt other means of anonymous reporting such as a dedicated email, all of which will only be accessed by the Chief Compliance Officer. The presence of the hotline and any other means of anonymous reporting will be posted in common work areas. Matters reported through any of these methods that suggest violations of the Compliance Program or legal requirements will be investigated promptly to determine their veracity.

C. Non-Retaliation

Aquestive does not tolerate any form of retaliation or intimidation against any colleague for raising a business practice issue in good faith or for participating in an investigation regarding a suspected violation. Aquestive reserves the right to discipline any colleague who knowingly makes a false accusation or deliberately provides false information about Aquestive.

VII. AUDITING AND MONITORING

Aquestive is committed to ensuring that its Compliance Program is earnestly implemented and enforced. As such, in addition to implementing education and training programs, policies, and notices, the Compliance Program includes monitoring and regular reporting to senior executives. Aquestive will perform regular, periodic audits of Aquestive's operations, with particular attention paid to billing, sales, marketing, and interactions with health care providers. The reviews will focus on those divisions or functions of Aquestive that have substantive involvement with or impact on state and federal health care programs and on the risk areas identified in this Compliance Program Manual. The reviews will also evaluate Aquestive's SOPs regarding other areas of concern identified by the OIG (e.g., through Special Fraud Alerts) and federal and state law enforcement agencies. Specifically, the reviews will evaluate: (1) whether there are sufficient policies covering the identified risk areas; (2) that such policies were implemented and communicated; and (3) the policies were followed.

Aquestive will employ numerous audit procedures, including but not limited to:

- confirming that required training done through an audit of participant records;
- auditing the Company's pricing arrangements with PBMs, GPOs, etc.;

- spot checking sales and marketing interactions with physicians and other potential prescribers;
- auditing employment and vendor records to confirm that no excluded or debarred individuals have been hired or retained; and
- reviewing contractual relationships, including research grants, with physicians.

VIII. COLLEAGUE OBLIGATIONS

Compliance is expected of all Aquestive Personnel, including Aquestive managers and supervisors. Aquestive will consider the promotion of and adherence to the Compliance Program when evaluating the performance of managers and supervisors within Aquestive. Any colleague, including a manager or supervisor, who violates the Compliance Program, including the Code of Conduct and SOPs, will be subject to appropriate disciplinary action which may include, but is not limited to, a performance improvement plan and may include termination, depending on the circumstances. Supervisors and managers, along with other Aquestive Personnel, will be periodically trained in new compliance SOPs. In addition, all managers and supervisors will: (1) discuss with all supervised colleagues, agents or vendors the compliance policies and legal requirements applicable to their function; (2) inform all supervised colleagues, agents, or vendors that strict compliance with these policies and requirements is a condition of employment or continued engagement; and (3) disclose to all supervised colleagues that Aquestive will take disciplinary action up to and including termination of employment (or termination of the contracted relationship for any agents or vendors) for violation of these policies or requirements.

IX. CORRECTIVE ACTION

A. <u>Investigating, Reporting and Correcting Identified Problems</u>

1. Investigation

Any suspected or actual violation of the Compliance Program, including the Code of Conduct and SOPs, failure to comply with federal and/or state laws, or other types of misconduct, will be promptly investigated, either by the Chief Compliance Officer or a senior manager, as appropriate. If a material violation has in fact occurred, appropriate steps will be taken to rectify it and report it to the government, if necessary. Depending on the nature of the allegations and circumstance, the Chief Compliance Officer and/or senior management may engage outside auditors or legal counsel to assist with the investigation.

If an investigation of an alleged violation is undertaken and the Chief Compliance Officer believes the integrity of the investigation may be at stake because of the presence of colleagues under investigation, the colleague(s) allegedly involved in the misconduct may be removed from his/her current work activity until the investigation is completed. In addition, the Chief Compliance Officer will take appropriate steps to prevent the destruction of documents or other evidence relevant to the investigation. Once an investigation is completed, if disciplinary action is warranted, it will be imposed in accordance with Aquestive's standards of disciplinary action.

2. Reporting

If management receives credible evidence of misconduct from any source and, after appropriate investigative inquiry, has reasonable grounds to believe that the misconduct either: (a) violates criminal law or (b) constitutes a material violation of federal and/or state laws, then Aquestive will report the existence of the misconduct to the appropriate governmental authority as soon as possible, but no later than as required by applicable law. Aquestive will fully cooperate with the government to correct and remedy the problem. If the investigation ultimately reveals that criminal activity may have occurred, the appropriate federal and/or state governmental authorities will be notified promptly. As discussed below, Aquestive will also take appropriate corrective action, including prompt restitution of any damages to the government and the imposition of appropriate disciplinary action.

3. Corrective Action

If an investigation reveals that misconduct occurred, corrective actions will be immediately initiated, including restitution of any overpayment to the appropriate federal and/or state health care program, as applicable.

X. SUMMARY

Compliance is everyone's responsibility. All Aquestive Personnel have an obligation to follow the federal and state laws that apply to Aquestive's business, the Compliance Program as set forth in this Compliance Program Manual, including the Code of Conduct and Aquestive SOPs. If you have any questions, it is your responsibility to ask your manager or seek out one of the many resources available to you. In addition to your manager, these resources include: (i) the Chief Compliance Officer; (ii) Human Resources; (iii) Director of Compliance; (iv) CFO and (v) Aquestive's confidential hotline 866-777-9040 or website www.whistleblowerservices.com/aqst.