INTEGRITY AGREEMENT
BETWEEN THE OFFICE OF INSPECTOR GENERAL
OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
TORRINGTON-WINSTED PEDIATRIC ASSOCIATES, P.C.

I. PREAMBLE

Torrington-Winsted Pediatric Associates, P.C. (Torrington-Winsted) hereby enters into this Integrity Agreement (Agreement) with the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS) to promote compliance by Torrington-Winsted's owners, officers, directors, associates, employees, contractors, and agents with the statutes, regulations, program requirements, and written directives of Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) (Federal health care program requirements). This commitment to promote compliance applies to any entity that Torrington-Winsted owns or in which Torrington-Winsted has a control interest, as defined in 42 U.S.C. § 1320a-3(a)(3), and Torrington-Winsted's and any such entity's Covered Persons as defined in Section II.C. Contemporaneously with this Agreement, Torrington-Winsted is entering into a Settlement Agreement with the United States, and this Agreement is incorporated by reference into the Settlement Agreement.

II. TERM OF THE AGREEMENT

A. The period of compliance obligations assumed by Torrington-Winsted under this Agreement shall be three years from the effective date of this Agreement. The effective date shall be the date on which the final signatory of this Agreement executes this Agreement (Effective Date). Each one-year period beginning with the one-year period following the Effective Date, shall be referred to as a "Reporting Period."

B. Sections VII, VIII, IX, X, and XI shall expire no later than 120 days from OIG's receipt of: (1) Torrington-Winsted's final annual report; or (2) any additional materials submitted by Torrington-Winsted pursuant to OIG's request, whichever is later.

C. The scope of this Agreement shall be governed by the following definitions:

1. "Covered Persons" includes:

a. all owners, officers, directors, associates, and employees of Torrington-Winsted; and

b. all contractors, agents, and other persons who provide patient care items or services or who perform billing or coding functions on behalf of Torrington-Winsted.

III. INTEGRITY OBLIGATIONS

Torrington-Winsted hereby agrees to establish a Compliance Program that, at a minimum, includes the following elements:

A. Compliance Contact

Within 60 days of the Effective Date of this Agreement, Torrington-Winsted shall designate a person to be responsible for compliance activities ("Compliance Contact"). Torrington-Winsted shall maintain a Compliance Contact for the term of this Agreement. The Compliance Contact shall be responsible for: (1) developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this Agreement and with Federal health care program requirements; (2) monitoring Torrington-Winsted's day-to-day compliance activities; and (3) meeting all reporting obligations created under this Agreement.

Torrington-Winsted shall report to OIG, in writing, any changes in the identity or job responsibilities of the Compliance Contact, or any actions or changes that would affect the Compliance Contact's ability to perform the duties necessary to meet the obligations in this Agreement, within 15 days after such change. The name, address, phone number, and a description of any other job responsibilities performed by the Compliance Contact shall be included in the Implementation Report.

B. Posting of Notice

Within the 90 days after the Effective Date, Torrington-Winsted shall post in a prominent place accessible to all patients and Covered Persons a notice detailing its commitment to comply with all Federal health care program requirements in the conduct of its business.

This notice shall also include the following information: (1) a means (e.g., telephone number or address) by which instances of misconduct may be reported anonymously; (2) Torrington-Winsted's commitment to maintain the confidentiality of the report; and (3) notification that reporting a suspected

violation will not result in retribution or retaliation by Torrington-Winsted. A copy of this notice shall be included in the Implementation Report.

C. Written Policies and Procedures

Within 90 days after the Effective Date, Torrington-Winsted shall develop, implement, and distribute written Policies and Procedures to all Covered Persons. In addition, Torrington-Winsted shall make the promotion of, and adherence to, the written Policies and Procedures an element in evaluating the performance of all employees. The written Policies and Procedures shall, at a minimum, set forth:

1. Torrington-Winsted's commitment to full compliance with all Federal health care program requirements, including its commitment to prepare and submit accurate claims consistent with such requirements;

2. Torrington-Winsted's requirement that all of its Covered Persons shall be expected to comply with all Federal health care program requirements and with Torrington-Winsted's own written Policies and Procedures as implemented pursuant to this Section III.C (including the requirements of this Agreement);

3. the responsibility and requirement that all of Torrington-Winsted's Covered Persons report suspected violations of any Federal health care program requirements or of Torrington-Winsted's own Policies and Procedures to the Compliance Contact and Torrington-Winsted's commitment to maintain confidentiality and anonymity, as appropriate, and not to retaliate with respect to such disclosures;

4. the possible consequences to both Torrington-Winsted and Covered Persons of failure to comply with Federal health care program requirements or with Torrington-Winsted's written Policies and Procedures and the failure to report such noncompliance;

5. Torrington-Winsted's commitment to remain current with all Federal health care program requirements by obtaining and reviewing program memoranda, newsletters, and any other correspondence from the carrier related to Federal health care program requirements;

6. the proper procedures for the accurate preparation and submission of claims in accordance with Federal health care program requirements; and

7. the applicable Federal health care program requirements relating to the management and accountability of vaccines under the Vaccines for Children Program, including, but not limited to, proper billing and payment procedures for vaccines.

Within 90 days after the Effective Date, each Covered Person shall certify in writing that he or she has received, read, understood, and shall abide by Torrington-Winsted's written Policies and Procedures. New Covered Persons shall receive and review the written Policies and Procedures and shall complete the required certification within 30 days after becoming a Covered Person or within 90 days after the Effective Date, whichever is later.

At least annually (and more frequently if appropriate), Torrington-Winsted shall assess and update, as necessary, the Policies and Procedures. Within 30 days after the effective date of any revisions, the relevant portions of any such revised Policies and Procedures shall be distributed to all Covered Persons. Appropriate and knowledgeable staff shall be available to explain the Policies and Procedures.

Copies of the written Policies and Procedures shall be included in the Implementation Report. Copies of any written Policies and Procedures that are subsequently revised shall be included in the next Annual Report along with a summary of any change or amendment to each Policy and Procedure required by this Section and the reason for each change.

D. Training and Certification

Within 90 days after the Effective Date and at least once each year thereafter, Torrington-Winsted and Covered Persons shall receive at least three hours of training from an individual or entity, other than another Covered Person. Persons providing the training shall be knowledgeable about the relevant subject area.

New Covered Persons shall receive the training described above within 30 days after becoming a Covered Person or within 90 days after the Effective Date, whichever is later. The training for new Covered Persons may either be provided internally by a Covered Person who has completed the required annual training or externally by a qualified individual or entity. A new Covered Person shall work under the direct supervision of a Covered Person who has received such training, to the extent that the work relates to the delivery of patient care items or services and/or the preparation or submission of claims for reimbursement from any Federal health care program, until such time as the new Covered Person completes the training.

At a minimum, the initial, annual, and new employee training sessions shall include the following topics:

1. the requirements of Torrington-Winsted's Agreement;

2. an overview of Torrington-Winsted's compliance program;

3. the accurate coding and submission of claims for services rendered and/or items provided to Federal health care program beneficiaries;

4. applicable reimbursement statutes, regulations, and program requirements and directives;

5. the written Policies and Procedures developed pursuant to Section III.C, above;

6. the personal obligation of each individual involved in the coding and claims submission process to ensure that such claims are accurate;

7. the legal sanctions for the submission of improper claims or violations of the Federal health care program requirements;

8. examples of proper and improper coding and claim submission practices; and

9. the Federal health care program requirements relating to vaccine management and accountability under the Vaccines for Children Program, including, but not limited to, proper billing and payment procedures for vaccines.

Each Covered Person shall annually certify, in writing or in electronic format if the training is computerized, that he or she has received the required training. The certification shall specify the date the training was received. The Compliance Contact shall retain the certifications, along with all training materials. Torrington-Winsted shall annually review the training, and, where appropriate, update the training to reflect changes in Federal health care program requirements.

Torrington-Winsted may provide the training required under this Agreement through appropriate computer-based training approaches. If Torrington-Winsted chooses to provide computer-based training, it shall make available

appropriately qualified and knowledgeable staff or trainers to answer questions or provide additional information to the individuals receiving such training.

The training materials shall be provided to the OIG in the Implementation Report, and to the extent the training is revised, shall also be included in the Annual Reports. The certifications shall be made available to OIG, upon request.

E. Management and Accountability of Vaccines

This Section III.E of the Agreement pertains specifically to vaccines received free of charge from the Vaccines for Children Program (hereinafter referred to as "Vaccines"). Within 90 days following the Effective Date of this Agreement, Torrington-Winsted shall assess its internal procedures relating to the management and accountability of Vaccines. If necessary, Torrington-Winsted shall establish and implement, or revise, internal procedures so they are reasonably designed to track the receipt, storage, inventory, use, and financial disposition of Vaccines.

As part of the Implementation Report, Torrington-Winsted shall describe the general procedures used to track the receipt, storage, use, inventory, and financial disposition of Vaccines. In addition, Torrington-Winsted shall report the following information:

1. the aggregate number of Vaccines received during the Reporting Period;

2. the entity or individual who provided each type of Vaccine;

3. the specific manner in which each Vaccine was used. For example, if Torrington-Winsted used the Vaccine to treat patients, Torrington-Winsted shall list the name of each patient, the source of the patient's insurance (if any), the number of Vaccines used to treat each patient, the date(s) of such use, and the manner in which the patient or any insurer was charged (if at all) for the sample. If the Vaccines were used to replace a damaged or expired product, Torrington-Winsted shall provide the number of Vaccines used in this manner, the date of the replacement, and the number of units of product, if any, returned to the manufacturer. If the Vaccines were used for training purposes, Torrington-Winsted shall identify to whom the training was provided, the date(s) on which the training was provided, and how many Vaccines were used in providing such training. If Torrington-Winsted uses the Vaccines in any other manner, it shall describe, in detail, the manner in which those Vaccines were used; and

4. a certification by the Compliance Contact that Torrington-Winsted has complied with the applicable Federal health care program requirements relating to the management and accountability of Vaccines.

In the event the OIG has reason to believe that: (i) Torrington-Winsted's management and accountability of Vaccines fails to conform to the requirements of this Agreement; or (ii) the Vaccine information reported in accordance with this Section III.E is inaccurate, the OIG may, at its sole discretion, conduct its own review to determine whether Torrington-Winsted's management and accountability of Vaccines complies with the requirements of the Agreement and/or the Vaccine information reported pursuant to Section III.E. is accurate ("Validation Review"). Torrington-Winsted agrees to pay for the reasonable cost of any such review performed by the OIG or any of its designated agents so long as it is initiated before one year after the final Annual Report is received by the OIG.

Prior to initiating a Validation Review, the OIG shall notify Torrington-Winsted of its intent to do so and provide a written explanation of why the OIG believes such a review is necessary. To resolve any concerns raised by the OIG, Torrington-Winsted may request a meeting with the OIG to discuss the underlying issues about Torrington-Winsted's compliance with the requirements of this Agreement; present any additional or relevant information; and/or propose alternatives to the proposed Validation Review. Torrington-Winsted agrees to provide any additional information as may be requested by the OIG under this section in an expedited manner. The OIG will attempt in good faith to resolve any issues related to the requirements of the Agreement with Torrington-Winsted prior to conducting a Validation Review. However, the final determination as to whether or not to proceed with a Validation Review shall be made at the sole discretion of the OIG.

F. Ineligible Persons

1. Definitions. For purposes of this Agreement:

a. An "Ineligible Person" shall include an individual or entity who:

i. is currently excluded, debarred, suspended, or otherwise ineligible to participate in the Federal health care programs or in Federal procurement or nonprocurement programs; or

ii. has been convicted of a criminal offense that falls within the ambit of 42 U.S.C. § 1320a-7(a), but has not yet been

excluded, debarred, suspended, or otherwise declared ineligible.

b. "Exclusion Lists" include:

i. the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at http://oig.hhs.gov); and

ii. the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at http://www.epls.arnet.gov)

2. Screening Requirements. Torrington-Winsted shall ensure that all prospective and current owners, officers, directors, associates, employees, contractors, and agents of Torrington-Winsted are not Ineligible Persons. To ensure that such individuals and entities are not Ineligible Persons, Torrington-Winsted shall require such individuals and entities to disclose immediately any debarment, exclusion, suspension, or other event that makes such individual or entity an Ineligible Person. Prior to engaging the services of such individuals and entities, Torrington-Winsted shall screen such individuals and entities against the Exclusion Lists. In addition, Torrington-Winsted shall:

a. Within 90 days after the Effective Date, review its list of individuals and entities identified in Section III.F.2 against the Exclusion Lists; and

b. Review its list of individuals and entities identified in Section III.F.2 against the Exclusion Lists annually.

Torrington-Winsted shall maintain documentation demonstrating that: (i) it has checked the Exclusion Lists (e.g., print screens from search results) and determined that such individuals or entities are not Ineligible Persons; and (ii) has required individuals and entities to disclose if they are an Ineligible Person (e.g., employment applications). Nothing in this Section affects the responsibility of (or liability for) Torrington-Winsted to refrain from billing Federal health care programs for services of the Ineligible Person.

3. Removal Requirement. If Torrington-Winsted has notice that any individual or entity in one of the positions identified in Section III.F.2 has become an Ineligible Person, Torrington-Winsted shall remove such individual or entity from responsibility for, or involvement with, Torrington-Winsted's business operations related to the Federal health care

programs and shall remove such individual or entity from any position for which the individual's or entity's compensation or the items or services rendered, ordered, or prescribed by the individual or entity are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds at least until such time as the individual or entity is reinstated into participation in the Federal health care programs.

4. Pending Charges and Proposed Exclusions. If Torrington-Winsted has notice that an individual identified in Section III.F.2 is charged with a criminal offense that falls within the ambit of 42 U.S.C. § 1320a-7(a), or an individual or entity identified in Section III.F.2 is proposed for exclusion during his, her or its employment, involvement or contract term, Torrington-Winsted shall take all appropriate actions to ensure that the responsibilities of that individual or entity has not and shall not adversely affect the quality of care rendered to any beneficiary, patient, or resident, or the accuracy of any claims submitted to any Federal health care program.

G. Notification of Government Investigation or Legal Proceedings

Within 30 days after discovery, Torrington-Winsted shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to Torrington-Winsted conducted or brought by a governmental entity or its agents involving an allegation that Torrington-Winsted has committed a crime or has engaged in fraudulent activities. This notification shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding. Torrington-Winsted shall also provide written notice to OIG within 30 days after the resolution of the matter, and shall provide OIG with a description of the findings and/or results of the proceedings, if any.

H. Reporting

1. Overpayments

a. *Definition of Overpayments*. For purposes of this Agreement, an "Overpayment" shall mean the amount of money Torrington-Winsted has received in excess of the amount due and payable under any Federal health care program requirements.

b. *Reporting of Overpayments*. If, at any time, Torrington-Winsted identifies or learns of any Overpayment, Torrington-Winsted shall notify the payor (e.g., Medicare fiscal intermediary or carrier) within 30 days after identification of the Overpayment and take remedial

steps within 60 days after identification (or such additional time as may be agreed to by the payor) to correct the problem, including preventing the underlying problem and the Overpayment from recurring. Also, within 30 days after identification of the Overpayment, Torrington-Winsted shall repay the Overpayment to the appropriate payor to the extent such Overpayment has been quantified. If not yet quantified within 30 days after identification, Torrington-Winsted shall notify the payor at that time of its efforts to quantify the Overpayment amount along with a schedule of when such work is expected to be completed. Notification and repayment to the payor shall be done in accordance with the payor's policies, and for Medicare contractors shall include the information contained on the Overpayment Refund Form, provided as Appendix A to this Agreement. Notwithstanding the above, notification and repayment of any Overpayment amount that routinely is reconciled or adjusted pursuant to policies and procedures established by the payor should be handled in accordance with such policies and procedures.

2. Reportable Events.

a. *Definition of Reportable Event.* For purposes of this Agreement, a "Reportable Event" means anything that involves:

i. a substantial Overpayment; or

ii. a matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any Federal health care program for which penalties or exclusion may be authorized.

A Reportable Event may be the result of an isolated event or a series of occurrences.

b. *Reporting of Reportable Event.* If Torrington-Winsted determines (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a Reportable Event, Torrington-Winsted shall notify OIG, in writing, within 30 days after making the determination that the Reportable Event exists. The report to OIG shall include the following information:

i. If the Reportable Event results in an Overpayment, the report to OIG shall be made at the same time as the

notification to the payor required in Section III.H.1, and shall include all of the information on the Overpayment Refund Form, as well as:

(A) the payor's name, address, and contact person to whom the Overpayment was sent; and

(B) the date of the check and identification number (or electronic transaction number) by which the Overpayment was repaid/refunded;

ii. a complete description of the Reportable Event, including the relevant facts, persons involved, and legal and Federal health care program authorities implicated;

iii. a description of Torrington-Winsted's actions taken to correct the Reportable Event; and

iv. any further steps Torrington-Winsted plans to take to address the Reportable Event and prevent it from recurring.

I. Third Party Billing

1. Current Contract with Third Party Biller. If Torrington-Winsted presently contracts with a third party billing company to submit claims to the Federal health care programs, Torrington-Winsted represents that it does not have an ownership or control interest (as defined in 42 U.S.C. § 1320a-3(a)(3)) in the third party billing company and is not employed by, and does not act as a consultant to, the third party billing company. If Torrington-Winsted intends to obtain an ownership or control interest (as defined in 42 U.S.C. § 1320a-3(a)(3)) in, or become employed by, or become a consultant to, any third party billing company during the term of this Agreement, Torrington Winsted shall notify OIG 30 days prior to any such proposed involvement.

Within 90 days after the Effective Date, Torrington-Winsted shall obtain (and provide to OIG in the Implementation Report) a certification from the third party billing company that the company:

(a) is presently in compliance with all Federal health care program requirements as they relate to the submission of claims to Federal health care programs;

(b) has a policy of not employing any person who is excluded, debarred, suspended or otherwise ineligible to participate in Medicare or other Federal health care programs to perform any duties related directly or indirectly to the preparation or submission of claims to Federal health care programs; and

(c) provides the required training in accordance with Section III.D of the Agreement for those employees involved in the preparation and submission of claims to Federal health care programs.

If Torrington-Winsted contracts with a new third party billing company during the term of this Agreement, Torrington-Winsted shall, within 30 days of entering into such contract, obtain and send to OIG the certification described in this Section III.I.1.

IV. NEW BUSINESS UNITS OR LOCATIONS

In the event that, after the Effective Date, Torrington-Winsted changes locations or sells, closes, purchases, or establishes a new business unit or location related to the furnishing of items or services that may be reimbursed by Federal health care programs, Torrington-Winsted shall notify OIG of this fact as soon as possible, but no later than 30 days after the date of change of location, sale, closure, purchase, or establishment. This notification shall include the address of the new business unit or location, phone number, fax number, Medicare and Medicaid provider numbers, provider identification number, and/or supplier number, and the corresponding contractor's name and address that issued each number. Each new business unit or location and all Covered Persons at each new business unit or location shall be subject to the applicable requirements in this Agreement.

Prior to Torrington-Winsted becoming an employee or contractor with another party related to Torrington-Winsted's furnishing of items or services that may be reimbursed by Federal health care programs, Torrington-Winsted shall notify that party of this Agreement. This notification shall include a copy of the Agreement, a statement indicating the remaining term of the Agreement, and a summary of Torrington-Winsted's obligations under the Agreement. In addition, Torrington-Winsted shall notify OIG of such relationship in its next Annual Report.

V. IMPLEMENTATION AND ANNUAL REPORTS

A. Implementation Report

Within 120 days after the Effective Date, Torrington-Winsted shall submit a written report to OIG summarizing the status of its implementation of the

requirements of this Agreement (Implementation Report). The Implementation Report shall, at a minimum, include:

1. the Compliance Contact's name, address, and phone number, a description of any other job responsibilities performed by the Compliance Contact, and the date the Compliance Contact was appointed;

2. a copy of the notice Torrington-Winsted posted in its office as required by Section III.B, a description of where the notice is posted, and the date the notice was posted;

3. a copy of the written Policies and Procedures required by Section III.C of this Agreement and the date these Policies and Procedures were implemented and distributed;

4. a copy of the general procedures relating to the management and accountability of Vaccines required by Section III.E;

5. a copy of all training materials used for the training session(s) required by Section III.D, a description of the training, including a summary of the topics covered, the length of each session, and a schedule of when the training session(s) were held;

6. a description of Torrington-Winsted's process to screen Covered Persons to determine if they are ineligible;

7. a summary of personnel actions (other than hiring) taken pursuant to Section III.F, the name, title, and responsibilities of any person who is determined to be an Ineligible Person under Section III.F, and the actions taken in response to the obligations set forth in Section III.F;

8. a list of all Torrington-Winsted's locations (including locations and mailing addresses), the corresponding name under which each location is doing business, the corresponding phone numbers and fax numbers, each location's Medicare provider number(s), provider identification number(s), and/or supplier number(s), and the name and address of each contractor to which Torrington-Winsted currently submits claims;

9. if Torrington-Winsted became a contractor with another party related to the furnishing of items or services that may be reimbursed by Federal health care programs, Torrington-Winsted shall inform OIG of the name, location, relationship, and its responsibilities with respect Torrington-Winsted's contract;

10. a certification by the Compliance Contact that:

a. the written Policies and Procedures required by Section III.C of this Agreement have been developed, are being implemented, and have been distributed to all Covered Persons; and that all Covered Persons have executed the written Policies and Procedures certification in accordance with the timeframe required by Section III.C of this Agreement;

b. all Covered Persons have completed the applicable training required by Section III.D of this Agreement; and that all Covered Persons have executed the applicable training certification(s) in accordance with the timeframe required by Section III.D of this Agreement;

c. all owners, officers, directors, associates, employees, contractors, and agents that were hired or engaged since the execution of the Agreement were screened against the Exclusion Lists and asked to disclose if they are excluded, debarred, suspended, or are otherwise considered an Ineligible Person, prior to entering into their relationship with Torrington-Winsted, as required by Section III.F of this Agreement;

d. all current owners, officers, directors, associates, employees, contractors, and agents of Torrington-Winsted were screened against the Exclusion Lists within 90 days after the Effective Date of this Agreement, as required by Section III.F of this Agreement and the date(s) of the screening; and

e. Torrington-Winsted has complied with the applicable Federal health care program requirements relating to the management and accountability of Vaccines.

11. a certification signed by the Compliance Contact that Torrington-Winsted certifying (a) to the best of his or her knowledge, except as otherwise described in the Implementation Report, Torrington-Winsted is in compliance with all of the requirements of this Agreement and (b) he or she has reviewed the Implementation Report and has made a reasonable inquiry regarding its content and believes that the information is accurate and truthful.

B. Annual Reports

Torrington-Winsted shall submit to the OIG Annual Reports with respect to the status of and findings regarding its compliance activities for each of the three one-year reporting periods beginning on the Effective Date of the Agreement. (The one-year period covered by each Annual Report shall be referred to as "the Reporting Period"). The first Annual Report shall be received by the OIG no later than 60 days after the end of the first Reporting Period. Subsequent Annual Reports shall be received by the OIG no later than the anniversary date of the due date of the first Annual Report.

Each Annual Report shall include:

1. any change in the name, address, phone number, or job responsibilities of Torrington-Winsted's Compliance Contact;

2. any changes to the posted notice and the reason for such changes;

3. a copy of any new compliance-related Policies and Procedures;

4. a summary of any changes or amendments to the written Policies and Procedures required by Section III.C and the reason(s) for such changes (e.g., change in contractor policies);

5. a summary of any changes or amendments to the general procedures relating to the management and accountability of Vaccines required by Section III.E;

6. a copy of all training materials used for the training session(s) required by Section III.D (to the extent they have not already been provided as part of the Implementation Report); a description of the training, including a summary of the topics covered; the length of each session; and a schedule of when the training session(s) was held;

7. a description of Torrington-Winsted's process to screen Covered Persons to determine if they are ineligible (to the extent it has changed from the Implementation Report);

8. a summary of personnel actions/other than hiring taken pursuant to Section III.F; the name, titles, and responsibilities of any person who is determined to be an Ineligible Person under Section III.F; and Torrington-Winsted's actions taken in response to the obligations set forth in Section III.F;

9. a summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to Section III.G. The summary shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding;

10. a summary of Reportable Events (as defined in Section III.H) identified during the Reporting Period and the status of any corrective and preventative action relating to all such Reportable Events;

11. a report of the aggregate Overpayments that have been returned to the Federal health care programs. Overpayment amounts shall be broken down into the following categories: Medicare, Medicaid, and other Federal health care programs;

12. a description of all changes to the most recently provided list of Torrington-Winsted's locations (including addresses) as required by Section IV. Include the corresponding name under which each location is doing business, the corresponding phone numbers, fax numbers, each location's Medicare provider number(s), provider identification number(s), and/or supplier number(s), and the name and address of the contractor that issued each number;

13. if Torrington-Winsted became a contractor with another party related to the furnishing of items or services that may be reimbursed by Federal health care programs, Torrington-Winsted shall inform OIG of the name, location, relationship, and its responsibilities with respect to Torrington-Winsted's contract;

14. a certification, where appropriate, by the Compliance Contact that certifies that:

a. the written Policies and Procedures have been reviewed during the Reporting Period, as required by Section III.C of this Agreement, and that all Covered Persons have executed the written Policies and Procedures certification in accordance with the timeframe required by Section III.C of this Agreement;

b. all Covered Persons have completed the applicable training required by Section III.D of this Agreement and that all Covered Persons have executed the applicable training certification(s) in accordance with the timeframe required by Section III.D of this

Agreement;

c. all owners, officers, directors, associates, employees, contractors, and agents that were hired, engaged or otherwise involved with Torrington-Winsted during the Reporting Period have been screened against the Exclusion Lists and asked to disclose if they are excluded, debarred, suspended, or are otherwise considered an Ineligible Person, prior to entering into their relationship with Torrington-Winsted, as required by Section III.F of this Agreement;

d. all owners, officers, directors, associates, employees, contractors, and agents (employed, engaged, or otherwise involved with Torrington-Winsted for the entire Reporting Period) were screened against the Exclusion Lists during the Reporting Period, in accordance with Section III.F of this Agreement and the date(s) they were screened;

e. Torrington-Winsted has complied with its obligations under the Settlement Agreement: (1) not to resubmit to any Federal health care program payors any previously denied claims related to the Covered Conduct addressed in the Settlement Agreement, and not to appeal any such denials of claims; (2) not to charge to or otherwise seek payment from Federal or State payors for unallowable costs (as defined in the Settlement Agreement); and (3) to identify and adjust any past charges or claims for unallowable costs; and

f. Torrington-Winsted has complied with the applicable Federal health care program requirements relating to the management and accountability of Vaccines.

15. a certification signed by the Compliance Contact certifying that (a) to the best of his or her knowledge, except as otherwise described in the applicable Report, Torrington-Winsted is in compliance with all of the requirements of this Agreement and (b) he or she has reviewed the Annual Report and has made a reasonable inquiry regarding its content and believes that the information is accurate and truthful.

VI. NOTIFICATIONS AND SUBMISSION OF REPORTS

Unless otherwise stated subsequent to the execution of this Agreement, all notifications and reports required under the terms of this Agreement shall be submitted to the following:

For the OIG: Administrative and Civil Remedies Branch
Office of Counsel to the Inspector General
Office of Inspector General
U.S. Department of Health and Human Services
Cohen Building, Room 5527
330 Independence Avenue, S.W.
Washington, DC 20201
Telephone: 202.619.2078
Facsimile: 202.205.0604

For Torrington-Winsted:

Attention: Compliance Contact
Torrington-Winsted Pediatric Associates, P.C.
538 Litchfield Street, Suite G-02
Torrington, CT 06790
Telephone: 860.489.5068
Facsimile: 860.489.3725

Unless otherwise specified, all notifications and reports required by this Agreement may be made by certified mail, overnight mail, hand delivery, or other means, provided that there is proof that such notification was received. For purposes of this requirement, internal facsimile confirmation sheets do not constitute proof of receipt.

VII. OIG INSPECTION, AUDIT, AND REVIEW RIGHTS

In addition to any other rights the OIG may have by statute, regulation, or contract, the OIG or its duly authorized representative(s) may examine or request copies of Torrington-Winsted's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of Torrington-Winsted's locations for the purpose of verifying and evaluating: (1) Torrington-Winsted's compliance with the terms of this Agreement; and (2) Torrington-Winsted's compliance with the requirements of the Federal health care programs in which it participates. The documentation described above shall be made available by Torrington-Winsted to the OIG or its duly authorized representative(s) at all reasonable times for inspection, audit, or reproduction. Furthermore, for purposes of this provision, the OIG or its duly authorized representative(s) may interview any of Torrington-Winsted's employees, contractors, or agents who consent to be interviewed at the individual's place of business during normal business hours or at such other place and time as may be mutually agreed upon between the individual and the OIG. Torrington-Winsted agrees to assist the OIG or its duly authorized representative(s) in contacting and

arranging interviews with such individuals upon the OIG's request. Torrington-Winsted's employees may elect to be interviewed with or without a representative of Torrington-Winsted present.

VIII. DOCUMENT AND RECORD RETENTION

Torrington-Winsted shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs, or to compliance with this Agreement, for four years (or longer if otherwise required by law).

IX. DISCLOSURES

Consistent with HHS's Freedom of Information Act (FOIA) procedures, set forth in 45 C.F.R. Part 5, OIG shall make a reasonable effort to notify Torrington-Winsted prior to any release by OIG of information submitted by Torrington-Winsted pursuant to its obligations under this Agreement and identified upon submission by Torrington-Winsted as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, Torrington-Winsted shall have the rights set forth at 45 C.F.R. § 5.65(d).

X. BREACH AND DEFAULT PROVISIONS

Torrington-Winsted is expected to fully and timely comply with all of its Agreement obligations.

A. Stipulated Penalties for Failure to Comply with Certain Obligations

As a contractual remedy, Torrington-Winsted and OIG hereby agree that failure to comply with certain obligations set forth in this Agreement (unless a timely written request for an extension has been requested and approved in accordance with Section B below) may lead to the imposition of the following monetary penalties (hereinafter referred to as "Stipulated Penalties") in accordance with the following provisions.

1. A Stipulated Penalty of $750 (which shall begin to accrue on the day after the date the obligation became due) for each day Torrington-Winsted fails to:

   a. have a Compliance Contact in accordance with the requirements of Section III.A;

   b. establish and/or post a notice in accordance with the requirements

of Section III.B;

c. establish, implement, maintain, distribute and/or update the written Policies and Procedures in accordance with the requirements of Section III.C;

d. establish and implement a training program in accordance with the requirements of Section III.D;

e. obtain and/or maintain the following documentation: Policies and Procedures certifications in accordance with the requirements of Section III.C, training certification(s) in accordance with the requirements of Section III.D, and/or documentation of screening and disclosure requirements in accordance with the requirements of Section III.F.2;

f. screen current or prospective owners, officers, directors, associates, employees, contractors, or agents in accordance with the requirements of Section III.F; or require owners, officers, directors, associates, employees, contractors, or agents to disclose if they are debarred, excluded, suspended, or are otherwise considered an Ineligible Person in accordance with the requirements of Section III.F; or

g. notify OIG of a Government investigation or legal proceeding, in accordance with the requirements of Section III.G.

2. A Stipulated Penalty of $1,000 (which shall begin to accrue on the day after the date the obligation became due) for each day Torrington-Winsted fails to submit the Implementation Report or Annual Reports to OIG in accordance with the requirements of Section V by the deadlines for submission.

3. A Stipulated Penalty of $750 for each day Torrington-Winsted fails to grant access to the information or documentation as required in Section VII. (This Stipulated Penalty shall begin to accrue on the date Torrington-Winsted fails to grant access.)

4. A Stipulated Penalty of $5,000 for each false certification submitted by or on behalf of Torrington-Winsted as part of its Implementation Report, Annual Reports, additional documentation to a report (as requested by OIG), or as otherwise required by this Agreement.

5. A Stipulated Penalty of $750 for each day Torrington-Winsted fails to

comply fully and adequately with any obligation of this Agreement. OIG shall provide notice (Notice) to Torrington-Winsted stating the specific grounds for its determination that Torrington-Winsted has failed to comply fully and adequately with the Agreement obligation(s) at issue and the steps Torrington-Winsted shall take to comply with the Agreement. (This Stipulated Penalty shall begin to accrue 10 days after the date Torrington-Winsted receives this Notice from OIG of the failure to comply.) A Stipulated Penalty as described in this Subsection shall not be demanded for any violation for which OIG has sought a Stipulated Penalty under Subsections 1-4 of this Section.

B. Timely Written Requests for Extensions

Torrington-Winsted may, in advance of the due date, submit a timely written request for an extension of time to perform any act or file any notification or report required by this Agreement. Notwithstanding any other provision in this Section, if OIG grants the timely written request with respect to an act, notification, or report, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until one day after Torrington-Winsted fails to meet the revised deadline set by OIG. Notwithstanding any other provision in this Section, if OIG denies such a timely written request, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until three business days after Torrington-Winsted receives OIG's written denial of such request or the original due date, whichever is later. A "timely written request" is defined as a request in writing received by OIG at least five business days prior to the date by which any act is due to be performed or any notification or report is due to be filed.

C. Payment of Stipulated Penalties.

1. Demand Letter. Upon a finding that Torrington-Winsted has failed to comply with any of the obligations described in Section X.A and after determining that Stipulated Penalties are appropriate, OIG shall notify Torrington-Winsted of: (a) Torrington-Winsted's failure to comply; and (b) OIG's exercise of its contractual right to demand payment of the Stipulated Penalties (this notification is referred to as the "Demand Letter").

2. Response to Demand Letter. Within 10 days of the receipt of the Demand Letter, Torrington-Winsted shall either: (a) cure the breach to OIG's satisfaction and pay the applicable Stipulated Penalties; or (b) send in writing to OIG a request for a hearing before an HHS administrative law judge (ALJ) to dispute OIG's determination of noncompliance, pursuant to

the agreed upon provisions set forth below in Section X.E. In the event Torrington-Winsted elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Torrington-Winsted cures, to OIG's satisfaction, the alleged breach in dispute. Failure to respond to the Demand Letter in one of these two manners within the allowed time period shall be considered a material breach of this Agreement and shall be grounds for exclusion under Section X.D.

3. Form of Payment. Payment of the Stipulated Penalties shall be made by certified or cashier's check, payable to: "Secretary of the Department of Health and Human Services," and submitted to OIG at the address set forth in Section VI.

4. Independence from Material Breach Determination. Except as set forth in Section X.D.1.c, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for OIG's decision that Torrington-Winsted has materially breached this Agreement, which decision shall be made at OIG's discretion and shall be governed by the provisions in Section X.D, below.

D. Exclusion for Material Breach of this Agreement

1. Definition of Material Breach. A material breach of this Agreement means:

a. a failure by Torrington-Winsted to report a Reportable Event, take corrective action and make the appropriate refunds, as required in Section III.H;

b. a repeated or flagrant violation of the obligations under this Agreement, including, but not limited to, the obligations addressed in Section X.A; or

c. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section X.C.

2. Notice of Material Breach and Intent to Exclude. The parties agree that a material breach of this Agreement by Torrington-Winsted constitutes an independent basis for Torrington-Winsted's exclusion from participation in the Federal health care programs. Upon a determination by OIG that Torrington-Winsted has materially breached this Agreement and that exclusion is the appropriate remedy, OIG shall notify Torrington-Winsted of:

a. Torrington-Winsted's material breach; and

b. OIG's intent to exercise its contractual right to impose exclusion (this notification is hereinafter referred to as the "Notice of Material Breach and Intent to Exclude").

3. Opportunity to Cure. Torrington-Winsted shall have 30 days from the date of receipt of the Notice of Material Breach and Intent to Exclude to demonstrate to OIG's satisfaction that:

a. Torrington-Winsted is in compliance with the obligations of the Agreement cited by OIG as being the basis for the material breach;

b. the alleged material breach has been cured; or

c. the alleged material breach cannot be cured within the 30-day period, but that: (i) Torrington-Winsted has begun to take action to cure the material breach; (ii) Torrington-Winsted is pursuing such action with due diligence; and (iii) Torrington-Winsted has provided to OIG a reasonable timetable for curing the material breach.

4. Exclusion Letter. If at the conclusion of the 30-day period, Torrington-Winsted fails to satisfy the requirements of Section X.D.3, OIG may exclude Torrington-Winsted from participation in the Federal health care programs. OIG shall notify Torrington-Winsted in writing of its determination to exclude Torrington-Winsted (this letter shall be referred to hereinafter as the "Exclusion Letter"). Subject to the Dispute Resolution provisions in Section X.E, below, the exclusion shall go into effect 30 days after the date of Torrington-Winsted's receipt of the Exclusion Letter. The exclusion shall have national effect and shall also apply to all other Federal procurement and nonprocurement programs. Reinstatement to program participation is not automatic. After the end of the period of exclusion, Torrington-Winsted may apply for reinstatement, by submitting a written request for reinstatement in accordance with the provisions at 42 C.F.R. §§ 1001.3001-.3004.

E. Dispute Resolution

1. Review Rights. Upon OIG's delivery to Torrington-Winsted of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this Agreement, Torrington-Winsted shall be afforded certain review rights comparable to

the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. Part 1005 as if they applied to the Stipulated Penalties or exclusion sought pursuant to this Agreement. Specifically, OIG's determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an HHS ALJ and, in the event of an appeal, the HHS Departmental Appeals Board (DAB), in a manner consistent with the provisions in 42 C.F.R. §§ 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving Stipulated Penalties shall be made within 10 days after the receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days after receipt of the Exclusion Letter.

2. Stipulated Penalties Review. Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under this Agreement shall be: (a) whether Torrington-Winsted was in full and timely compliance with the obligations of this Agreement for which OIG demands payment; and (b) the period of noncompliance. Torrington-Winsted shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. OIG shall not have the right to appeal to the DAB an adverse ALJ decision related to Stipulated Penalties. If the ALJ agrees with OIG with regard to a finding of a breach of this Agreement and orders Torrington-Winsted to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless Torrington-Winsted requests review of the ALJ decision by the DAB. If the ALJ decision is properly appealed to the DAB and the DAB upholds the determination of OIG, the Stipulated Penalties shall become due and payable 20 days after the DAB issues its decision.

3. Exclusion Review. Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding for exclusion based on a material breach of this Agreement shall be:

a. whether Torrington-Winsted was in material breach of this Agreement;

b. whether such breach was continuing on the date of the Exclusion Letter; and

c. whether the alleged material breach could not have been cured within the 30-day period, but that: (i) Torrington-Winsted had

begun to take action to cure the material breach within that period; (ii) Torrington-Winsted has pursued and is pursuing such action with due diligence; and (iii) Torrington-Winsted provided to OIG within that period a reasonable timetable for curing the material breach and Torrington-Winsted has followed the timetable.

For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision favorable to OIG, or, if the ALJ rules for Torrington-Winsted, only after a DAB decision in favor of OIG. Torrington-Winsted's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude Torrington-Winsted upon the issuance of an ALJ's decision in favor of OIG. If the ALJ sustains the determination of OIG and determines that exclusion is authorized, such exclusion shall take effect 20 days after the ALJ issues such a decision, notwithstanding that Torrington-Winsted may request review of the ALJ decision by the DAB. If the DAB finds in favor of OIG after an ALJ decision adverse to OIG, the exclusion shall take effect 20 days after the DAB decision. Torrington-Winsted shall waive its right to any notice of such an exclusion if a decision upholding the exclusion is rendered by the ALJ or DAB. If the DAB finds in favor of Torrington-Winsted, Torrington-Winsted shall be reinstated effective on the date of the original exclusion.

4. Finality of Decision. The review by an ALJ or DAB provided for above shall not be considered to be an appeal right arising under any statutes or regulations. Consequently, the parties to this Agreement agree that the DAB's decision (or the ALJ's decision if not appealed) shall be considered final for all purposes under this Agreement.

XI. EFFECTIVE AND BINDING AGREEMENT

Consistent with the provisions in the Settlement Agreement pursuant to which this Agreement is entered, and into which this Agreement is incorporated, Torrington-Winsted and OIG agree as follows:

A. This Agreement shall be binding on the successors, assigns, and transferees of Torrington-Winsted.

B. This Agreement shall become final and binding on the date the final signature is obtained on the Agreement.

C. Any modifications to this Agreement shall be made with the prior written consent of the parties to this Agreement.

D. OIG may agree to a suspension of Torrington-Winsted's obligations under this Agreement in the event of Torrington-Winsted's cessation of participation in Federal health care programs. If Torrington-Winsted withdraws from participation in Federal health care programs and is relieved of its Agreement obligations by OIG, Torrington-Winsted shall notify OIG 30 days in advance of Torrington-Winsted's intent to reapply as a participating provider or supplier with any Federal health care program. Upon receipt of such notification, OIG shall evaluate whether the Agreement shall be reactivated or modified.

E. All requirements and remedies set forth in this Agreement are in addition to, and do not effect, (1) Torrington-Winsted's responsibility to follow all applicable Federal health care program requirements or (2) the Government's right to impose appropriate remedies for failure to follow applicable program requirements.

F. The undersigned Torrington-Winsted signatories represent and warrant that they are authorized to execute this Agreement. The undersigned OIG signatory represents that he is signing this Agreement in his official capacity and that he is authorized to execute this Agreement.

IN WITNESS WHEREOF, the parties hereto affix their signatures:

FOR TORRINGTON-WINSTED PEDIATRIC ASSOCIATES, P.C.

Edward C. Kavle, M.D.
President

11/30/04
DATE

Jason M. Parkal, M.D.

11/30/04
DATE

FOR THE OFFICE OF INSPECTOR GENERAL OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES

LEWIS MORRIS
Chief Counsel to the Inspector General
Office of Counsel to the Inspector General
Office of Inspector General
U.S. Department of Health and Human Services

12/8/04
DATE